

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Overall		Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	5 / 327 (1.5%)	5 / 327 (1.5%)
		OR (95% CI) p value	1.0000 (0.2867, 3.4875) 1.000	
		RD (95% CI) p value	0.0000 (-1.8809, 1.8809) 1.000	
		RR (95% CI) p value	1.0000 (0.2923, 3.4215) 1.000	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates.

By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Statistical estimates are unadjusted.

PPD

Table 2.01
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA \geq 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Age (years)	<35	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	2 / 84 (2.4%)	1 / 98 (1.0%)
	35 - <50	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3 / 154 (1.9%)	2 / 143 (1.4%)
	\geq 50	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	0 / 89	2 / 86 (2.3%)

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates.

By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

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Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Sex at Birth	Female	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3 / 73 (4.1%)	0 / 75
	Male	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	2 / 254 (0.8%)	5 / 252 (2.0%)

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates.

By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Statistical estimates are unadjusted.

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Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Race	White	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	2 / 238 (0.8%)	5 / 256 (2.0%)
	Non-White	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3 / 89 (3.4%)	0 / 71

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates.
 By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Statistical estimates are unadjusted.

Table 2.01
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 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Region	North America	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	3 / 118 (2.5%)	3 / 135 (2.2%)
	Europe	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	1 / 165 (0.6%)	2 / 155 (1.3%)
	Rest of World	Number of Subjects with HIV-1 RNA \geq 50 c/mL/Total Assessed	1 / 44 (2.3%)	0 / 37

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Zero counts for subjects with HIV-1 RNA \geq 50 c/mL in either treatment group may lead to unreliable statistical estimates.

By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Statistical estimates are unadjusted.

PPD

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Overall		Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	306 / 327 (93.6%)	300 / 327 (91.7%)
		OR (95% CI) p value	1.3114 (0.7254, 2.3707) 0.369	
		RD (95% CI) p value	1.8349 (-2.1600, 5.8297) 0.368	
		RR (95% CI) p value	1.0200 (0.9769, 1.0650) 0.369	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Age (years)	<35	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	78 / 84 (92.9%)	89 / 98 (90.8%)
		OR (95% CI)	1.3146 (0.4479, 3.8587)	
		p value	0.619	
		RD (95% CI)	2.0408 (-5.8980, 9.9796)	
		p value	0.614	
		RR (95% CI)	1.0225 (0.9377, 1.1149)	
		p value	0.615	
		p value for interaction	0.366	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Age (years)	35 - <50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	142 / 154 (92.2%)	133 / 143 (93.0%)
		OR (95% CI)	0.8897 (0.3720, 2.1277)	
		p value	0.793	
		RD (95% CI)	-0.7992 (-6.7485, 5.1501)	
		p value	0.792	
		RR (95% CI)	0.9914 (0.9297, 1.0572)	
		p value	0.792	
		p value for interaction	0.366	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Age (years)	>=50	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	86 / 89 (96.6%)	78 / 86 (90.7%)
		OR (95% CI)	2.9402 (0.7532, 11.4765)	
		p value	0.121	
		RD (95% CI)	5.9315 (-1.2619, 13.1250)	
		p value	0.106	
		RR (95% CI)	1.0654 (0.9854, 1.1518)	
		p value	0.112	
		p value for interaction	0.366	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Sex at Birth	Female	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	65 / 73 (89.0%)	65 / 75 (86.7%)
		OR (95% CI)	1.2500 (0.4639, 3.3682)	
		p value	0.659	
		RD (95% CI)	2.3744 (-8.1392, 12.8880)	
		p value	0.658	
		RR (95% CI)	1.0274 (0.9114, 1.1582)	
		p value	0.658	
		p value for interaction	0.881	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Sex at Birth	Male	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	241 / 254 (94.9%)	235 / 252 (93.3%)
		OR (95% CI)	1.3411 (0.6372, 2.8225)	
		p value	0.440	
		RD (95% CI)	1.6279 (-2.4872, 5.7430)	
		p value	0.438	
		RR (95% CI)	1.0175 (0.9739, 1.0630)	
		p value	0.439	
		p value for interaction	0.881	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Race	White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	225 / 238 (94.5%)	236 / 256 (92.2%)
		OR (95% CI)	1.4668 (0.7127, 3.0186)	
		p value	0.298	
		RD (95% CI)	2.3503 (-2.0248, 6.7255)	
		p value	0.292	
		RR (95% CI)	1.0255 (0.9785, 1.0748)	
		p value	0.293	
		p value for interaction	0.785	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

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Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Race	Non-White	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	81 / 89 (91.0%)	64 / 71 (90.1%)
		OR (95% CI)	1.1074 (0.3814, 3.2157)	
		p value	0.851	
		RD (95% CI)	0.8704 (-8.2616, 10.0024)	
		p value	0.852	
		RR (95% CI)	1.0097 (0.9128, 1.1168)	
		p value	0.852	
		p value for interaction	0.785	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

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Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Region	North America	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	110 / 118 (93.2%)	121 / 135 (89.6%)
		OR (95% CI)	1.5909 (0.6428, 3.9374)	
		p value	0.315	
		RD (95% CI)	3.5907 (-3.2667, 10.4481)	
		p value	0.305	
		RR (95% CI)	1.0401 (0.9647, 1.1213)	
		p value	0.306	
		p value for interaction	0.400	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Region	Europe	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	157 / 165 (95.2%)	144 / 155 (92.9%)
		OR (95% CI) p value	1.4991 (0.5866, 3.8315) 0.398	
		RD (95% CI) p value	2.2483 (-2.9556, 7.4522) 0.397	
		RR (95% CI) p value p value for interaction	1.0242 (0.9689, 1.0826) 0.398 0.400	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.02
 Analysis of Proportion of Subjects With Plasma HIV-1 RNA < 50 copies/mL (Snapshot) at Week 48 -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Measure	Q8W (N=327)	Q4W (N=327)
Region	Rest of World	Number of Subjects with HIV-1 RNA <50 c/mL/Total Assessed	39 / 44 (88.6%)	35 / 37 (94.6%)
		OR (95% CI)	0.4457 (0.0813, 2.4450)	
		p value	0.352	
		RD (95% CI)	-5.9582 (-17.8336, 5.9171)	
		p value	0.325	
		RR (95% CI)	0.9370 (0.8221, 1.0680)	
		p value	0.330	
		p value for interaction	0.400	

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD is obtained from the Freq procedure. OR and RR are obtained from genmod models (link = logit or log, respectively) for overall and subgroups (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment. Statistical estimates are unadjusted.

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Overall

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q8W	327	Baseline	327	688.6	265.95	643.0	496.0	849.0	163	1481
			Week 48	305	686.4	263.60	677.0	499.0	837.0	122	1580
			Change	305	-0.7	150.58	-3.0	-77.0	81.0	-622	532
	Q4W	327	Baseline	327	741.0	288.77	711.0	535.0	886.0	114	1823
			Week 48	298	715.9	287.37	678.0	535.0	876.0	34	2889
			Change	298	-19.2	204.93	-4.0	-101.0	66.0	-1049	1525

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

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
<35	Q8W	84	Baseline	84	669.7	232.91	634.5	505.5	821.0	220	1319
			Week 48	79	720.1	247.02	697.0	526.0	867.0	250	1416
			Change	79	53.3	132.53	43.0	-23.0	127.0	-411	431
	Q4W	98	Baseline	98	760.5	286.56	720.0	579.0	931.0	231	1782
			Week 48	88	723.5	264.32	686.0	549.5	897.5	34	1409
			Change	88	-41.1	223.08	-24.5	-123.5	77.0	-1049	454
35 - <50	Q8W	154	Baseline	154	710.5	267.50	665.0	533.0	897.0	163	1481
			Week 48	142	700.4	275.53	690.5	525.0	829.0	122	1580
			Change	142	-8.5	166.58	-5.5	-95.0	81.0	-622	532
	Q4W	143	Baseline	143	743.1	289.89	729.0	528.0	888.0	171	1823
			Week 48	131	714.7	255.11	673.0	534.0	879.0	169	1524
			Change	131	-24.3	177.69	-4.0	-101.0	56.0	-1005	599
>=50	Q8W	89	Baseline	89	668.5	291.31	620.0	432.0	826.0	217	1386
			Week 48	84	631.0	252.32	568.5	447.0	793.0	216	1340
			Change	84	-38.4	122.81	-34.0	-102.0	43.5	-436	249
	Q4W	86	Baseline	86	715.2	290.85	695.0	516.0	847.0	114	1699
			Week 48	79	709.4	357.70	641.0	526.0	817.0	243	2889
			Change	79	13.6	223.85	5.0	-82.0	81.0	-412	1525

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

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Female	Q8W	73	Baseline	73	702.0	289.55	630.0	529.0	915.0	163	1396
			Week 48	63	648.8	241.37	631.0	471.0	824.0	122	1223
			Change	63	-42.8	139.28	-33.0	-115.0	63.0	-477	249
	Q4W	75	Baseline	75	752.9	325.88	701.0	562.0	880.0	171	1823
			Week 48	65	741.2	377.59	661.0	550.0	840.0	249	2889
			Change	65	-4.6	281.02	3.0	-103.0	66.0	-1005	1525
Male	Q8W	254	Baseline	254	684.8	259.26	644.0	491.0	828.0	207	1481
			Week 48	242	696.2	268.69	689.0	507.0	840.0	216	1580
			Change	242	10.2	151.74	8.5	-65.0	83.0	-622	532
	Q4W	252	Baseline	252	737.4	277.38	719.0	535.0	887.0	114	1782
			Week 48	233	708.8	257.22	680.0	526.0	879.0	34	1661
			Change	233	-23.3	178.61	-4.0	-101.0	63.0	-1049	454

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

Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
White	Q8W	238	Baseline	238	696.3	263.58	647.0	499.0	861.0	198	1379
			Week 48	225	698.6	263.89	682.0	513.0	843.0	216	1580
			Change	225	4.9	151.45	1.0	-72.0	81.0	-622	532
	Q4W	256	Baseline	256	757.7	294.95	725.0	540.5	905.5	114	1823
			Week 48	235	717.8	262.41	665.0	526.0	886.0	34	1661
			Change	235	-33.8	188.71	-4.0	-114.0	63.0	-1049	454
Non-White	Q8W	89	Baseline	89	668.1	272.66	629.0	483.0	824.0	163	1481
			Week 48	80	652.1	261.35	664.0	461.5	827.0	122	1371
			Change	80	-16.6	147.87	-3.5	-100.0	64.5	-477	280
	Q4W	71	Baseline	71	680.8	258.35	677.0	488.0	822.0	231	1364
			Week 48	63	708.7	368.29	683.0	545.0	826.0	162	2889
			Change	63	34.9	251.01	5.0	-89.0	87.0	-348	1525

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

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Table 2.03
 Summary of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³) at Week 48
 - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	Actual		Mean	SD	Median	Q1	Q3	Min.	Max.
			Time	n							
North America	Q8W	118	Baseline	118	704.0	237.41	672.5	526.0	840.0	207	1396
			Week 48	111	696.5	239.93	689.0	522.0	845.0	216	1416
			Change	111	-5.3	145.05	-15.0	-69.0	63.0	-375	431
	Q4W	135	Baseline	135	768.4	277.54	757.0	535.0	943.0	231	1739
			Week 48	120	740.1	312.29	698.5	560.5	870.5	34	2889
			Change	120	-22.8	242.19	0.5	-112.0	63.0	-1049	1525
Europe	Q8W	165	Baseline	165	687.6	270.94	643.0	483.0	849.0	163	1386
			Week 48	155	693.5	273.67	684.0	499.0	835.0	122	1580
			Change	155	11.1	153.79	24.0	-67.0	91.0	-622	532
	Q4W	155	Baseline	155	725.1	299.04	686.0	554.0	863.0	114	1823
			Week 48	143	693.1	256.37	643.0	512.0	878.0	243	1524
			Change	143	-24.7	170.19	-6.0	-101.0	71.0	-1005	427
Rest of World	Q8W	44	Baseline	44	650.9	317.48	589.0	385.0	908.0	217	1481
			Week 48	39	629.6	286.19	544.0	423.0	829.0	233	1371
			Change	39	-34.5	151.07	-3.0	-122.0	56.0	-411	249
	Q4W	37	Baseline	37	707.1	284.20	677.0	473.0	866.0	241	1336
			Week 48	35	725.8	318.13	681.0	495.0	895.0	169	1661
			Change	35	15.2	198.02	5.0	-103.0	78.0	-348	599

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

Table 2.04
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 - Overall - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Hedges' g		
							Hedges' g (S.E)	95% CI	P-value
Q8W	327	305	-5.19	8.353	10.23 (-17.44, 37.90)	0.468	0.0627 (0.08136)	(-0.0972, 0.2225)	0.442
Q4W	327	298	-15.42	11.326					

[1] Adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from MMRM model with the following variables: treatment, visit, treatment*visit, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
		n	Mean[1] S.E				Hedges' g (S.E)	95% CI	P-value
Q8W	84	79	41.48 19.286	67.19 (15.11, 119.26)	0.012	0.043	0.2096 (0.15491)	(-0.0946, 0.5139)	0.177
Q4W	98	88	-25.70 18.159						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	154	142	-9.04	14.362	7.97 (-32.68, 48.61)	0.700	0.043	0.0319 (0.12099)	(-0.2057, 0.2695)	0.792
Q4W	143	131	-17.01	14.901						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	Adjusted		Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
		n	Mean[1] S.E				Hedges' g (S.E)	95% CI	P-value
Q8W	89	84	-44.08 18.715	-45.90 (-98.51, 6.70)	0.087	0.043	-0.1422 (0.15658)	(-0.4497, 0.1654)	0.364
Q4W	86	79	1.82 19.162						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	73	63	-45.02	21.427	-43.38 (-102.51, 15.76)	0.150	0.442	-0.1175 (0.17661)	(-0.4644, 0.2293)	0.506
Q4W	75	65	-1.64	21.149						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	254	242	5.17	11.107	23.15 (-7.91, 54.20)	0.144	0.442	0.1212 (0.09173)	(-0.0590, 0.3013)	0.187
Q4W	252	233	-17.98	11.234						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	238	225	2.37	11.503	26.75 (-4.81, 58.30)	0.096	0.079	0.1376 (0.09324)	(-0.0455, 0.3207)	0.141
Q4W	256	235	-24.38	11.195						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05

Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	Adjusted n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	89	80	-26.71	19.104	-48.25 (-104.72, 8.22)	0.094	0.079	-0.1386 (0.16828)	(-0.4691, 0.1919)	0.410
Q4W	71	63	21.53	21.510						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	118	111	-8.00	16.402	6.54 (-37.96, 51.04)	0.773	0.014	0.0238 (0.13152)	(-0.2345, 0.2821)	0.856
Q4W	135	120	-14.54	15.621						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	Adjusted n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	165	155	7.90	13.873	30.90 (-8.34, 70.15)	0.123	0.014	0.1281 (0.11586)	(-0.0994, 0.3557)	0.269
Q4W	155	143	-23.00	14.375						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 2.05
 Statistical Analysis of Change from Maintenance Baseline in CD4+ Cell Count (cells/mm³)
 at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Treatment	N	Adjusted n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Inter[3] P-value	Hedges' g		
								Hedges' g (S.E)	95% CI	P-value
Q8W	44	39	-50.04	27.431	-71.15 (-149.92, 7.63)	0.077	0.014	-0.1469 (0.23258)	(-0.6037, 0.3099)	0.528
Q4W	37	35	21.10	29.266						

[1] For each subgroup, adjusted mean is the estimated mean change from Baseline at Week 48 in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Baseline CD4+ cell count, with visit as the repeated factor. No assumptions were made about the correlations between subject readings of CD4+ cell count i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

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

Note: MMRM = Mixed Model Repeated Measures.

Table 3.25
 Analysis of Proportion of Subjects with any New Onset of an "HIV-infection stage 3"
 Event (Maintenance Phase) - Overall - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall	0/327	2/327 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q8W		327	Baseline	327	85.9	15.70	87.5	75.0	100.0	0	100
				Week 24	318	87.6	14.33	93.8	75.0	100.0	31	100
				Week 48	310	85.6	16.52	93.8	75.0	100.0	6	100
				W48 CFB	310	-0.5	15.04	0.0	-6.3	6.3	-75	100
	Q4W		327	Baseline	327	84.5	17.05	87.5	75.0	100.0	0	100
				Week 24	324	84.0	18.47	90.6	75.0	100.0	0	100
				Week 48	310	85.3	17.44	93.8	75.0	100.0	6	100
				W48 CFB	310	0.9	17.24	0.0	-6.3	6.3	-75	69

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years) <35	Q8W		84	Baseline	84	86.2	16.71	93.8	75.0	100.0	0	100	
				Week 24	81	85.2	16.25	87.5	75.0	100.0	31	100	
				Week 48	80	88.7	13.75	93.8	75.0	100.0	50	100	
				W48 CFB	80	3.1	17.11	0.0	0.0	6.3	-31	100	
	Q4W		98	Baseline	98	84.3	17.68	87.5	75.0	100.0	0	100	
				Week 24	97	83.1	18.25	87.5	75.0	100.0	38	100	
				Week 48	92	84.8	18.26	93.8	75.0	100.0	25	100	
				W48 CFB	92	1.0	16.86	0.0	-3.1	6.3	-75	69	
	35 - <50	Q8W		154	Baseline	154	85.2	15.77	87.5	75.0	100.0	13	100
					Week 24	148	88.7	13.01	93.8	75.0	100.0	44	100
					Week 48	144	82.9	18.31	87.5	75.0	100.0	6	100
					W48 CFB	144	-3.0	13.97	0.0	-6.3	3.1	-75	25
Q4W			143	Baseline	143	84.0	17.31	87.5	75.0	100.0	0	100	
				Week 24	141	83.7	18.39	87.5	75.0	100.0	0	100	
				Week 48	136	84.4	17.76	87.5	75.0	100.0	6	100	
				W48 CFB	136	0.5	18.52	0.0	-6.3	6.3	-44	69	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years) >=50	Q8W		89	Baseline	89	86.8	14.67	87.5	81.3	100.0	38	100
				Week 24	89	87.9	14.49	93.8	81.3	100.0	44	100
				Week 48	86	87.3	15.11	93.8	81.3	100.0	38	100
				W48 CFB	86	0.4	14.08	0.0	-6.3	6.3	-44	50
	Q4W		86	Baseline	86	85.8	15.97	87.5	75.0	100.0	31	100
				Week 24	86	85.5	18.97	93.8	75.0	100.0	19	100
				Week 48	82	87.3	15.94	93.8	75.0	100.0	38	100
				W48 CFB	82	1.7	15.53	0.0	-6.3	6.3	-31	56

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at Birth	Female	Q8W	73	Baseline	73	84.4	18.28	87.5	75.0	100.0	13	100
				Week 24	70	86.6	14.87	90.6	75.0	100.0	50	100
				Week 48	66	84.5	17.41	87.5	75.0	100.0	25	100
				W48 CFB	66	0.1	17.83	0.0	-6.3	6.3	-75	50
		Q4W	75	Baseline	75	82.8	20.22	87.5	75.0	100.0	0	100
				Week 24	74	83.4	20.07	90.6	75.0	100.0	19	100
				Week 48	66	84.8	17.65	90.6	75.0	100.0	31	100
				W48 CFB	66	3.1	19.06	0.0	-6.3	6.3	-44	69
	Male	Q8W	254	Baseline	254	86.3	14.88	87.5	75.0	100.0	0	100
				Week 24	248	87.8	14.20	93.8	75.0	100.0	31	100
				Week 48	244	85.9	16.30	93.8	75.0	100.0	6	100
				W48 CFB	244	-0.6	14.23	0.0	-6.3	6.3	-63	100
Q4W		252	Baseline	252	85.0	16.00	87.5	75.0	100.0	0	100	
			Week 24	250	84.2	18.00	90.6	75.0	100.0	0	100	
			Week 48	244	85.4	17.41	93.8	75.0	100.0	6	100	
			W48 CFB	244	0.4	16.70	0.0	-6.3	6.3	-75	69	

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	White	Q8W	238	Baseline	238	85.1	15.94	87.5	75.0	100.0	0	100
				Week 24	232	87.4	14.53	93.8	75.0	100.0	31	100
				Week 48	226	85.3	16.32	87.5	75.0	100.0	6	100
				W48 CFB	226	-0.1	14.67	0.0	-6.3	6.3	-63	100
		Q4W	256	Baseline	256	84.3	17.02	87.5	75.0	100.0	0	100
				Week 24	253	84.2	18.40	93.8	75.0	100.0	0	100
				Week 48	245	85.0	17.05	87.5	75.0	100.0	6	100
				W48 CFB	245	0.8	17.21	0.0	-6.3	6.3	-75	69
	Non-White	Q8W	89	Baseline	89	88.1	14.89	93.8	75.0	100.0	38	100
				Week 24	86	87.9	13.87	93.8	75.0	100.0	44	100
				Week 48	84	86.5	17.12	93.8	75.0	100.0	25	100
				W48 CFB	84	-1.5	16.05	0.0	-6.3	3.1	-75	56
	Q4W	71	Baseline	71	85.3	17.23	93.8	75.0	100.0	31	100	
			Week 24	71	83.1	18.82	87.5	75.0	100.0	25	100	
			Week 48	65	86.3	18.91	93.8	75.0	100.0	25	100	
			W48 CFB	65	1.4	17.46	0.0	0.0	6.3	-38	50	

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	North America	Q8W	118	Baseline	118	86.9	14.55	87.5	75.0	100.0	44	100
				Week 24	116	87.7	14.99	93.8	81.3	100.0	31	100
				Week 48	113	84.8	18.93	93.8	75.0	100.0	6	100
				W48 CFB	113	-2.0	14.48	0.0	-6.3	6.3	-75	31
		Q4W	135	Baseline	135	87.3	15.06	93.8	81.3	100.0	31	100
				Week 24	134	84.9	17.68	93.8	75.0	100.0	19	100
				Week 48	127	85.4	16.95	93.8	75.0	100.0	25	100
				W48 CFB	127	-1.9	15.32	0.0	-12.5	6.3	-38	63
	Europe	Q8W	165	Baseline	165	85.3	16.40	87.5	75.0	100.0	0	100
				Week 24	161	87.8	13.63	93.8	75.0	100.0	44	100
				Week 48	157	85.3	15.41	87.5	75.0	100.0	38	100
				W48 CFB	157	-0.6	14.96	0.0	-6.3	6.3	-44	100
	Q4W	155	Baseline	155	82.3	18.47	87.5	75.0	100.0	0	100	
			Week 24	154	83.5	18.44	87.5	75.0	100.0	0	100	
			Week 48	148	84.2	18.36	87.5	75.0	100.0	6	100	
			W48 CFB	148	2.2	18.40	0.0	-6.3	6.3	-75	69	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q8W	44	Baseline	44	85.4	16.17	90.6	75.0	100.0	38	100
				Week 24	41	86.0	15.36	87.5	75.0	100.0	56	100
				Week 48	40	89.2	12.97	93.8	81.3	100.0	50	100
				W48 CFB	40	4.5	16.20	0.0	0.0	6.3	-19	56
		Q4W	37	Baseline	37	83.8	16.63	87.5	75.0	100.0	50	100
				Week 24	36	82.6	21.60	90.6	71.9	100.0	25	100
				Week 48	35	89.6	14.69	100.0	81.3	100.0	38	100
				W48 CFB	35	6.3	17.35	0.0	0.0	12.5	-25	50

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q8W		327	Baseline	327	91.6	14.18	95.0	90.0	100.0	0	100
				Week 24	318	94.4	13.11	100.0	95.0	100.0	0	100
				Week 48	310	95.3	9.25	100.0	95.0	100.0	45	100
				W48 CFB	310	3.7	14.82	0.0	0.0	5.0	-50	100
	Q4W		327	Baseline	327	90.2	13.29	95.0	85.0	100.0	20	100
				Week 24	324	92.9	12.69	100.0	90.0	100.0	30	100
				Week 48	310	92.7	13.34	100.0	90.0	100.0	0	100
				W48 CFB	310	2.8	14.93	0.0	0.0	5.0	-75	80

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years) <35	Q8W		84	Baseline	84	92.0	12.49	95.0	90.0	100.0	50	100
				Week 24	81	96.2	8.74	100.0	100.0	100.0	55	100
				Week 48	80	96.6	6.04	100.0	95.0	100.0	70	100
				W48 CFB	80	4.4	11.06	0.0	0.0	7.5	-25	35
	Q4W		98	Baseline	98	89.7	12.31	95.0	80.0	100.0	50	100
				Week 24	97	91.0	14.36	100.0	90.0	100.0	30	100
				Week 48	92	91.7	15.18	100.0	90.0	100.0	0	100
				W48 CFB	92	2.1	15.45	0.0	0.0	5.0	-70	50
35 - <50	Q8W		154	Baseline	154	91.0	16.03	100.0	90.0	100.0	0	100
				Week 24	148	94.9	11.04	100.0	95.0	100.0	25	100
				Week 48	144	95.1	10.55	100.0	95.0	100.0	45	100
				W48 CFB	144	4.1	17.15	0.0	0.0	5.0	-50	100
	Q4W		143	Baseline	143	90.3	11.42	95.0	85.0	100.0	50	100
				Week 24	141	94.1	11.67	100.0	95.0	100.0	30	100
				Week 48	136	92.4	13.61	100.0	90.0	100.0	0	100
				W48 CFB	136	2.4	14.67	0.0	0.0	10.0	-75	40

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years) >=50	Q8W		89	Baseline	89	92.1	12.22	100.0	90.0	100.0	50	100
				Week 24	89	91.8	18.31	100.0	90.0	100.0	0	100
				Week 48	86	94.6	9.37	100.0	95.0	100.0	60	100
				W48 CFB	86	2.5	13.69	0.0	0.0	5.0	-40	50
	Q4W		86	Baseline	86	90.5	16.93	100.0	90.0	100.0	20	100
				Week 24	86	92.9	12.16	100.0	90.0	100.0	45	100
				Week 48	82	94.4	10.38	100.0	90.0	100.0	35	100
				W48 CFB	82	4.1	14.88	0.0	0.0	5.0	-30	80

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at Birth	Female	Q8W	73	Baseline	73	85.0	21.94	95.0	75.0	100.0	0	100
				Week 24	70	91.8	14.52	100.0	90.0	100.0	25	100
				Week 48	66	92.2	12.80	100.0	90.0	100.0	45	100
				W48 CFB	66	7.7	25.19	0.0	0.0	10.0	-50	100
		Q4W	75	Baseline	75	89.3	13.55	95.0	80.0	100.0	25	100
				Week 24	74	89.8	17.51	100.0	90.0	100.0	30	100
				Week 48	66	92.3	12.00	100.0	90.0	100.0	50	100
				W48 CFB	66	3.8	12.56	0.0	0.0	10.0	-30	40
	Male	Q8W	254	Baseline	254	93.4	10.29	100.0	90.0	100.0	45	100
				Week 24	248	95.1	12.61	100.0	95.0	100.0	0	100
				Week 48	244	96.2	7.85	100.0	95.0	100.0	50	100
				W48 CFB	244	2.6	10.19	0.0	0.0	5.0	-40	55
Q4W		252	Baseline	252	90.5	13.23	95.0	85.0	100.0	20	100	
			Week 24	250	93.8	10.74	100.0	90.0	100.0	40	100	
			Week 48	244	92.8	13.71	100.0	90.0	100.0	0	100	
			W48 CFB	244	2.5	15.53	0.0	0.0	5.0	-75	80	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	White	Q8W	238	Baseline	238	91.5	14.40	97.5	90.0	100.0	0	100
				Week 24	232	95.2	11.60	100.0	95.0	100.0	0	100
				Week 48	226	95.9	8.14	100.0	95.0	100.0	50	100
				W48 CFB	226	4.2	14.30	0.0	0.0	5.0	-30	100
		Q4W	256	Baseline	256	89.4	13.78	95.0	80.0	100.0	20	100
				Week 24	253	92.8	12.72	100.0	90.0	100.0	30	100
				Week 48	245	92.4	13.91	100.0	90.0	100.0	0	100
				W48 CFB	245	3.1	16.10	0.0	0.0	10.0	-75	80
	Non-White	Q8W	89	Baseline	89	91.6	13.63	95.0	90.0	100.0	50	100
				Week 24	86	92.2	16.39	100.0	95.0	100.0	15	100
				Week 48	84	93.9	11.65	100.0	90.0	100.0	45	100
				W48 CFB	84	2.5	16.14	0.0	0.0	5.0	-50	50
Q4W		71	Baseline	71	92.9	11.04	100.0	90.0	100.0	50	100	
			Week 24	71	92.9	12.64	100.0	90.0	100.0	50	100	
			Week 48	65	93.8	11.00	100.0	90.0	100.0	50	100	
			W48 CFB	65	1.5	9.30	0.0	0.0	5.0	-25	25	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	North America	Q8W	118	Baseline	118	92.6	11.47	95.0	90.0	100.0	50	100
				Week 24	116	92.5	17.98	100.0	95.0	100.0	0	100
				Week 48	113	95.3	9.14	100.0	95.0	100.0	50	100
				W48 CFB	113	2.3	11.40	0.0	0.0	5.0	-50	50
		Q4W	135	Baseline	135	92.2	12.54	100.0	90.0	100.0	20	100
				Week 24	134	95.0	9.75	100.0	95.0	100.0	50	100
				Week 48	127	94.6	9.51	100.0	90.0	100.0	50	100
				W48 CFB	127	2.6	12.67	0.0	0.0	5.0	-30	80
	Europe	Q8W	165	Baseline	165	90.5	16.40	100.0	90.0	100.0	0	100
				Week 24	161	95.4	9.12	100.0	95.0	100.0	55	100
				Week 48	157	95.3	9.68	100.0	95.0	100.0	45	100
				W48 CFB	157	4.8	16.92	0.0	0.0	5.0	-30	100
		Q4W	155	Baseline	155	88.6	13.46	95.0	80.0	100.0	25	100
				Week 24	154	91.4	14.17	100.0	90.0	100.0	30	100
				Week 48	148	91.4	14.43	97.5	87.5	100.0	0	100
				W48 CFB	148	3.1	15.89	0.0	-2.5	10.0	-75	50

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q8W	44	Baseline	44	93.0	11.43	100.0	90.0	100.0	50	100
				Week 24	41	95.6	9.10	100.0	95.0	100.0	50	100
				Week 48	40	95.6	7.94	100.0	90.0	100.0	60	100
				W48 CFB	40	3.4	14.47	0.0	0.0	10.0	-35	50
		Q4W	37	Baseline	37	89.5	14.57	95.0	80.0	100.0	50	100
				Week 24	36	91.0	14.68	100.0	85.0	100.0	40	100
				Week 48	35	91.6	19.01	100.0	90.0	100.0	0	100
				W48 CFB	35	2.1	18.40	0.0	-5.0	10.0	-70	50

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q8W		327	Baseline	326	65.3	30.16	75.0	40.0	90.0	0	100
				Week 24	318	66.0	30.10	75.0	45.0	90.0	0	100
				Week 48	310	64.4	31.78	70.0	40.0	95.0	0	100
				W48 CFB	309	-0.6	28.38	0.0	-10.0	10.0	-95	100
	Q4W		327	Baseline	327	65.7	30.72	75.0	40.0	95.0	0	100
				Week 24	324	67.0	31.26	77.5	40.0	95.0	0	100
				Week 48	310	65.2	31.31	75.0	40.0	90.0	0	100
				W48 CFB	310	-0.6	24.04	0.0	-10.0	10.0	-80	85

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years) <35	Q8W		84	Baseline	84	70.4	27.69	80.0	57.5	92.5	0	100	
				Week 24	81	70.5	27.78	80.0	50.0	90.0	0	100	
				Week 48	80	70.4	29.24	85.0	57.5	95.0	0	100	
				W48 CFB	80	-0.2	26.20	0.0	-7.5	10.0	-80	70	
	Q4W		98	Baseline	98	66.3	30.28	72.5	45.0	95.0	0	100	
				Week 24	97	66.2	31.84	75.0	45.0	95.0	0	100	
				Week 48	92	66.5	31.18	77.5	47.5	90.0	0	100	
				W48 CFB	92	0.1	28.12	0.0	-12.5	15.0	-80	85	
	35 - <50	Q8W		154	Baseline	154	60.7	31.64	65.0	35.0	90.0	0	100
					Week 24	148	61.2	31.29	65.0	35.0	90.0	0	100
					Week 48	144	59.2	31.60	62.5	30.0	90.0	0	100
					W48 CFB	144	-0.9	30.59	0.0	-10.0	10.0	-95	100
Q4W			143	Baseline	143	65.6	30.42	75.0	45.0	95.0	0	100	
				Week 24	141	67.7	30.11	80.0	45.0	95.0	0	100	
				Week 48	136	65.7	30.64	75.0	45.0	95.0	0	100	
				W48 CFB	136	-0.4	21.74	0.0	-10.0	10.0	-75	85	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Age (years) >=50	Q8W		89	Baseline	88	68.5	28.86	75.0	50.0	90.0	0	100
				Week 24	89	69.8	29.26	75.0	50.0	95.0	0	100
				Week 48	86	67.4	33.31	80.0	35.0	95.0	0	100
				W48 CFB	85	-0.6	26.75	0.0	-10.0	15.0	-75	60
	Q4W		86	Baseline	86	65.1	32.04	75.0	40.0	95.0	0	100
				Week 24	86	66.8	32.75	77.5	40.0	100.0	0	100
				Week 48	82	63.0	32.79	70.0	40.0	95.0	0	100
				W48 CFB	82	-1.6	22.96	0.0	-10.0	5.0	-60	80

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at Birth	Female	Q8W	73	Baseline	72	57.2	31.95	60.0	27.5	87.5	0	100
				Week 24	70	58.5	31.84	60.0	35.0	90.0	0	100
				Week 48	66	55.6	35.67	55.0	25.0	90.0	0	100
				W48 CFB	65	-1.1	36.98	0.0	-15.0	20.0	-95	70
		Q4W	75	Baseline	75	54.5	34.10	50.0	25.0	90.0	0	100
				Week 24	74	59.7	32.71	60.0	30.0	90.0	0	100
				Week 48	66	52.7	32.26	45.0	20.0	80.0	0	100
				W48 CFB	66	-1.2	20.68	0.0	-10.0	5.0	-60	50
	Male	Q8W	254	Baseline	254	67.6	29.30	75.0	50.0	95.0	0	100
				Week 24	248	68.1	29.32	75.0	50.0	90.0	0	100
				Week 48	244	66.8	30.29	75.0	50.0	95.0	0	100
				W48 CFB	244	-0.5	25.71	0.0	-10.0	10.0	-80	100
Q4W		252	Baseline	252	69.0	28.89	75.0	50.0	95.0	0	100	
			Week 24	250	69.2	30.55	80.0	45.0	95.0	0	100	
			Week 48	244	68.6	30.23	80.0	52.5	95.0	0	100	
			W48 CFB	244	-0.4	24.91	0.0	-10.0	10.0	-80	85	

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

PPD

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	White	Q8W	238	Baseline	237	64.2	29.73	70.0	40.0	90.0	0	100
				Week 24	232	65.6	29.63	72.5	40.0	90.0	0	100
				Week 48	226	65.4	31.03	75.0	40.0	90.0	0	100
				W48 CFB	225	1.3	27.72	0.0	-5.0	15.0	-90	100
		Q4W	256	Baseline	256	66.3	29.69	75.0	45.0	95.0	0	100
				Week 24	253	69.0	30.18	80.0	45.0	95.0	0	100
				Week 48	245	66.3	30.77	75.0	45.0	95.0	0	100
				W48 CFB	245	-0.2	24.35	0.0	-10.0	10.0	-75	85
	Non-White	Q8W	89	Baseline	89	68.4	31.24	80.0	40.0	95.0	0	100
				Week 24	86	67.0	31.51	75.0	50.0	95.0	0	100
				Week 48	84	61.7	33.76	65.0	30.0	95.0	0	100
				W48 CFB	84	-5.7	29.67	0.0	-20.0	10.0	-95	60
Q4W		71	Baseline	71	63.6	34.35	75.0	30.0	100.0	0	100	
			Week 24	71	60.0	34.11	70.0	30.0	90.0	0	100	
			Week 48	65	61.1	33.20	70.0	35.0	90.0	0	100	
			W48 CFB	65	-2.0	22.95	0.0	-10.0	5.0	-80	45	

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

Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	North America	Q8W	118	Baseline	118	72.1	28.10	80.0	50.0	95.0	0	100
				Week 24	116	71.4	29.55	85.0	52.5	95.0	0	100
				Week 48	113	69.5	29.59	80.0	50.0	95.0	0	100
				W48 CFB	113	-2.1	24.52	0.0	-10.0	10.0	-75	65
		Q4W	135	Baseline	135	69.6	29.51	75.0	50.0	95.0	0	100
				Week 24	134	73.7	29.34	85.0	50.0	100.0	0	100
				Week 48	127	72.3	29.91	85.0	55.0	95.0	0	100
				W48 CFB	127	2.5	22.94	0.0	-10.0	10.0	-75	85
	Europe	Q8W	165	Baseline	164	61.7	30.31	70.0	37.5	85.0	0	100
				Week 24	161	63.3	29.55	70.0	40.0	90.0	0	100
				Week 48	157	62.3	31.76	70.0	35.0	90.0	0	100
				W48 CFB	156	0.3	31.00	0.0	-10.0	17.5	-95	100
		Q4W	155	Baseline	155	60.6	30.85	65.0	35.0	85.0	0	100
				Week 24	154	60.0	31.71	65.0	35.0	90.0	0	100
				Week 48	148	57.9	31.26	60.0	30.0	85.0	0	100
				W48 CFB	148	-3.0	26.32	0.0	-15.0	10.0	-80	85

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

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Table 6.01

Summary of Quality of Life (HATQoL) in Life Satisfaction, HIV Medication, and Disclosure Worries by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q8W	44	Baseline	44	60.7	32.34	62.5	32.5	90.0	0	100
				Week 24	41	61.0	32.23	65.0	35.0	95.0	0	100
				Week 48	40	58.3	36.37	65.0	20.0	100.0	0	100
				W48 CFB	40	0.0	28.40	0.0	-10.0	12.5	-75	60
		Q4W	37	Baseline	37	72.7	31.90	85.0	55.0	100.0	5	100
				Week 24	36	72.4	30.62	82.5	55.0	95.0	0	100
				Week 48	35	70.6	30.29	80.0	55.0	95.0	0	100
				W48 CFB	35	-1.4	15.70	0.0	-5.0	5.0	-40	45

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

Table 6.02

Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Life Satisfaction Transformed Total Score

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q8W	327	310	-0.23	0.791	-0.64 (-2.93, 1.65)	0.581	-0.0444 (0.08023)	(-0.2020, 0.1131)	0.580
Q4W	327	310	0.41	0.855					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, treatment*visit, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

Table 6.02

Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: HIV Medication Transformed Total Score

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q8W	327	310	4.10	0.521	2.38 (0.62, 4.13)	0.008	0.2313 (0.08052)	(0.0731, 0.3895)	0.004
Q4W	327	310	1.72	0.726					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, treatment*visit, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

Table 6.02

Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48 - Overall - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Domain: Disclosure Worries Transformed Total Score

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q8W	327	309	-0.64	1.465	-0.11 (-3.91, 3.69)	0.954	-0.0047 (0.08029)	(-0.1623, 0.1530)	0.954
Q4W	327	310	-0.52	1.260					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, treatment*visit, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
<35	Q8W	84	80	3.04 (1.545)	3.29 (-1.05, 7.62)	0.137	0.715	0.1203 (0.15272)	(-0.1796, 0.4202)	0.431
	Q4W	98	92	-0.25 (1.578)						
35 - <50	Q8W	154	144	-2.83 (1.144)	-2.72 (-6.11, 0.68)	0.117	0.715	-0.1277 (0.11948)	(-0.3624, 0.1069)	0.285
	Q4W	143	136	-0.11 (1.295)						
>=50	Q8W	89	86	1.06 (1.482)	-0.94 (-5.32, 3.43)	0.673	0.715	-0.0343 (0.15416)	(-0.3370, 0.2685)	0.824
	Q4W	86	82	2.00 (1.668)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Female	Q8W	73	66	-0.65 (1.718)	-1.66 (-6.60, 3.27)	0.508	0.624	-0.0531 (0.17387)	(-0.3945, 0.2884)	0.760
	Q4W	75	66	1.01 (1.852)						
Male	Q8W	254	244	-0.11 (0.893)	-0.36 (-2.95, 2.23)	0.785	0.624	-0.0221 (0.09043)	(-0.1997, 0.1555)	0.807
	Q4W	252	244	0.25 (0.969)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
White	Q8W	238	226	-0.22 (0.927)	-0.51 (-3.14, 2.11)	0.702	0.954	-0.0309 (0.09212)	(-0.2118, 0.1500)	0.737
	Q4W	256	245	0.29 (0.964)						
Non-White	Q8W	89	84	-0.30 (1.526)	-1.26 (-5.98, 3.46)	0.601	0.954	-0.0430 (0.16499)	(-0.3671, 0.2810)	0.794
	Q4W	71	65	0.96 (1.867)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
North America	Q8W	118	113	-1.33 (1.326)	-0.17 (-3.84, 3.49)	0.926	0.883	-0.0075 (0.12916)	(-0.2611, 0.2462)	0.954
	Q4W	135	127	-1.16 (1.336)						
Europe	Q8W	165	157	-0.59 (1.130)	-1.19 (-4.45, 2.07)	0.475	0.883	-0.0579 (0.11444)	(-0.2827, 0.1668)	0.613
	Q4W	155	148	0.59 (1.259)						
Rest of World	Q8W	44	40	4.33 (2.267)	-1.03 (-7.62, 5.57)	0.760	0.883	-0.0250 (0.23117)	(-0.4789, 0.4290)	0.914
	Q4W	37	35	5.36 (2.568)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
<35	Q8W	84	80	5.12 (1.033)	4.62 (1.31, 7.93)	0.006	0.027	0.2353 (0.15283)	(-0.0649, 0.5355)	0.124
	Q4W	98	92	0.50 (1.333)						
35 - <50	Q8W	154	144	4.15 (0.763)	2.71 (0.10, 5.33)	0.042	0.027	0.1795 (0.11953)	(-0.0553, 0.4143)	0.134
	Q4W	143	136	1.43 (1.093)						
>=50	Q8W	89	86	3.09 (0.988)	-0.50 (-3.88, 2.87)	0.769	0.027	-0.0258 (0.15413)	(-0.3286, 0.2770)	0.867
	Q4W	86	82	3.59 (1.409)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Female	Q8W	73	66	2.78 (1.146)	1.18 (-2.61, 4.97)	0.542	0.879	0.0527 (0.17384)	(-0.2888, 0.3942)	0.762
	Q4W	75	66	1.60 (1.570)						
Male	Q8W	254	244	4.47 (0.592)	2.68 (0.70, 4.67)	0.008	0.879	0.2312 (0.09069)	(0.0531, 0.4094)	0.011
	Q4W	252	244	1.78 (0.821)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
White	Q8W	238	226	4.54 (0.610)	3.06 (1.06, 5.07)	0.003	0.146	0.2596 (0.09244)	(0.0780, 0.4412)	0.005
	Q4W	256	245	1.48 (0.818)						
Non-White	Q8W	89	84	2.81 (1.002)	0.02 (-3.65, 3.69)	0.992	0.146	0.0009 (0.16494)	(-0.3231, 0.3250)	0.995
	Q4W	71	65	2.79 (1.586)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
North America	Q8W	118	113	3.48 (0.885)	0.46 (-2.35, 3.26)	0.750	0.013	0.0275 (0.12914)	(-0.2262, 0.2812)	0.832
	Q4W	135	127	3.02 (1.139)						
Europe	Q8W	165	157	4.28 (0.754)	3.72 (1.20, 6.24)	0.004	0.013	0.2559 (0.11468)	(0.0306, 0.4812)	0.026
	Q4W	155	148	0.56 (1.071)						
Rest of World	Q8W	44	40	5.22 (1.521)	3.39 (-1.74, 8.52)	0.195	0.013	0.1163 (0.23114)	(-0.3378, 0.5704)	0.615
	Q4W	37	35	1.83 (2.187)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
<35	Q8W	84	80	1.64 (2.896)	1.74 (-5.55, 9.02)	0.640	0.414	0.0384 (0.15268)	(-0.2614, 0.3383)	0.801
	Q4W	98	92	-0.09 (2.323)						
35 - <50	Q8W	154	144	-2.48 (2.148)	-2.47 (-8.12, 3.17)	0.389	0.414	-0.0694 (0.11944)	(-0.3040, 0.1652)	0.561
	Q4W	143	136	0.00 (1.907)						
>=50	Q8W	89	85	0.37 (2.793)	2.24 (-5.05, 9.54)	0.546	0.414	0.0487 (0.15461)	(-0.2549, 0.3523)	0.753
	Q4W	86	82	-1.87 (2.457)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Female	Q8W	73	65	-3.20 (3.204)	1.33 (-6.86, 9.52)	0.750	0.970	0.0256 (0.17454)	(-0.3171, 0.3684)	0.883
	Q4W	75	66	-4.53 (2.729)						
Male	Q8W	254	244	0.06 (1.651)	-0.48 (-4.77, 3.81)	0.826	0.970	-0.0177 (0.09043)	(-0.1953, 0.1598)	0.845
	Q4W	252	244	0.54 (1.433)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

PPD

Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
White	Q8W	238	225	0.76 (1.718)	0.70 (-3.68, 5.07)	0.755	0.754	0.0255 (0.09222)	(-0.1556, 0.2066)	0.782
	Q4W	256	245	0.07 (1.422)						
Non-White	Q8W	89	84	-4.78 (2.816)	-2.70 (-10.41, 5.01)	0.492	0.754	-0.0552 (0.16501)	(-0.3793, 0.2688)	0.738
	Q4W	71	65	-2.08 (2.750)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

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Table 6.03
 Statistical Analysis of Quality of Life (HATQoL) - Change from Maintenance Baseline in
 Life Satisfaction, HIV Medication, and Disclosure Worries at Week 48
 - by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
North America	Q8W	118	113	1.08 (2.465)	-2.98 (-9.10, 3.13)	0.338	0.178	-0.0786 (0.12918)	(-0.3323, 0.1751)	0.543
	Q4W	135	127	4.06 (1.952)						
Europe	Q8W	165	156	-2.02 (2.102)	3.48 (-1.89, 8.86)	0.204	0.178	0.1029 (0.11464)	(-0.1223, 0.3280)	0.370
	Q4W	155	148	-5.50 (1.847)						
Rest of World	Q8W	44	40	0.61 (4.194)	-2.42 (-13.29, 8.44)	0.662	0.178	-0.0353 (0.23118)	(-0.4893, 0.4187)	0.879
	Q4W	37	35	3.03 (3.769)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HATQoL scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

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Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Overall	Q8W		327	Baseline	327	57.7	9.21	60.0	54.0	65.0	21	66
				Week 24	319	62.4	6.20	65.0	61.0	66.0	12	66
				Week 48	310	62.8	5.41	65.0	62.0	66.0	32	66
				W48 CFB	310	4.9	9.40	2.5	0.0	8.0	-34	45
	Q4W		327	Baseline	326	56.7	9.34	59.0	51.0	65.0	20	66
				Week 24	324	61.2	7.13	64.0	59.0	66.0	24	66
				Week 48	309	60.9	7.71	64.0	59.0	66.0	24	66
				W48 CFB	308	4.1	9.42	2.0	0.0	8.0	-28	44

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

Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.	
Age (years)	<35	Q8W	84	Baseline	84	57.5	8.76	60.0	54.0	64.0	23	66	
				Week 24	81	62.5	4.89	64.0	61.0	66.0	40	66	
				Week 48	80	62.3	5.02	64.5	59.5	66.0	38	66	
				W48 CFB	80	4.4	8.04	2.5	0.0	8.5	-26	27	
		Q4W	98	Baseline	98	54.7	9.89	57.0	48.0	64.0	20	66	
			Week 24	97	60.7	7.68	64.0	60.0	65.0	30	66		
			Week 48	91	60.5	7.61	63.0	58.0	66.0	28	66		
			W48 CFB	91	5.2	9.53	4.0	-1.0	11.0	-16	44		
		35 - <50	Q8W	154	Baseline	154	56.8	9.81	59.0	52.0	65.0	21	66
				Week 24	149	62.2	5.87	65.0	60.0	66.0	17	66	
				Week 48	144	62.4	6.32	65.0	62.0	66.0	32	66	
				W48 CFB	144	5.3	10.61	3.0	0.0	10.0	-34	45	
	Q4W		143	Baseline	142	56.3	9.73	59.0	51.0	65.0	26	66	
			Week 24	141	61.2	7.17	64.0	59.0	66.0	24	66		
			Week 48	136	60.4	8.35	64.0	57.0	66.0	24	66		
			W48 CFB	135	4.3	10.40	2.0	0.0	9.0	-28	36		
	>=50	Q8W	89	Baseline	89	59.4	8.37	62.0	55.0	66.0	22	66	
			Week 24	89	62.6	7.71	66.0	63.0	66.0	12	66		
			Week 48	86	63.9	3.71	66.0	63.0	66.0	50	66		
			W48 CFB	86	4.5	8.41	2.0	0.0	7.0	-15	44		
		Q4W	86	Baseline	86	59.7	7.15	63.0	55.0	66.0	34	66	
			Week 24	86	61.7	6.43	65.0	59.0	66.0	33	66		
			Week 48	82	62.2	6.55	65.0	60.0	66.0	28	66		
			W48 CFB	82	2.4	7.22	1.0	0.0	5.0	-20	22		

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

Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Sex at Birth	Female	Q8W	73	Baseline	73	55.7	11.85	59.0	54.0	65.0	21	66
				Week 24	70	62.5	5.21	65.0	61.0	66.0	40	66
				Week 48	66	62.4	6.38	65.0	62.0	66.0	32	66
				W48 CFB	66	6.1	12.18	2.5	0.0	8.0	-34	44
		Q4W	75	Baseline	74	57.6	8.24	59.5	53.0	65.0	34	66
				Week 24	74	62.0	6.75	65.0	62.0	66.0	36	66
	Male	Q8W	254	Baseline	254	58.3	8.23	60.5	54.0	65.0	21	66
				Week 24	249	62.4	6.47	65.0	61.0	66.0	12	66
				Week 48	244	62.9	5.12	65.0	61.5	66.0	34	66
				W48 CFB	244	4.6	8.49	2.5	0.0	8.0	-26	45
		Q4W	252	Baseline	252	56.5	9.64	59.0	50.5	65.0	20	66
				Week 24	250	61.0	7.23	64.0	59.0	66.0	24	66
				Week 48	243	60.8	7.78	64.0	59.0	66.0	24	66
				W48 CFB	243	4.3	9.68	2.0	0.0	8.0	-28	44

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

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Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Race	White	Q8W	238	Baseline	238	56.9	9.32	59.0	53.0	64.0	21	66
				Week 24	233	62.4	6.07	65.0	61.0	66.0	12	66
				Week 48	226	63.1	4.58	66.0	62.0	66.0	43	66
				W48 CFB	226	5.9	9.11	4.0	0.0	10.0	-23	45
		Q4W	256	Baseline	255	56.3	9.59	59.0	51.0	65.0	20	66
				Week 24	253	61.3	6.60	64.0	59.0	66.0	30	66
				Week 48	244	60.9	7.78	64.0	59.0	66.0	24	66
				W48 CFB	243	4.4	9.83	2.0	0.0	9.0	-28	44
	Non-White	Q8W	89	Baseline	89	59.8	8.61	63.0	57.0	66.0	22	66
				Week 24	86	62.5	6.59	65.0	62.0	66.0	17	66
				Week 48	84	61.8	7.11	65.0	61.0	66.0	32	66
				W48 CFB	84	2.0	9.61	0.0	-1.0	4.0	-34	44
Q4W		71	Baseline	71	58.2	8.28	61.0	51.0	66.0	36	66	
			Week 24	71	60.7	8.79	64.0	60.0	66.0	24	66	
			Week 48	65	61.0	7.51	64.0	59.0	66.0	37	66	
			W48 CFB	65	2.7	7.59	1.0	0.0	6.0	-17	25	

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

Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	North America	Q8W	118	Baseline	118	59.3	8.01	61.0	55.0	66.0	23	66
				Week 24	116	62.1	8.09	65.0	61.0	66.0	12	66
				Week 48	113	62.7	5.75	65.0	63.0	66.0	32	66
				W48 CFB	113	3.2	8.62	2.0	0.0	6.0	-34	36
	Europe	Q4W	135	Baseline	135	58.1	9.23	61.0	52.0	66.0	28	66
				Week 24	134	62.0	6.84	64.0	61.0	66.0	24	66
				Week 48	127	61.9	6.71	65.0	61.0	66.0	37	66
				W48 CFB	127	3.5	8.84	1.0	0.0	7.0	-18	30
		Q8W	165	Baseline	165	56.2	9.84	59.0	52.0	64.0	21	66
				Week 24	162	62.7	4.59	65.0	61.0	66.0	40	66
				Week 48	157	62.8	4.87	65.0	61.0	66.0	44	66
				W48 CFB	157	6.4	9.78	4.0	0.0	10.0	-12	45
Q4W	155	Baseline	154	55.9	9.08	57.0	51.0	64.0	26	66		
		Week 24	154	60.7	7.27	64.0	58.0	66.0	30	66		
		Week 48	147	60.4	8.27	64.0	57.0	66.0	24	66		
		W48 CFB	146	4.5	9.53	4.0	0.0	10.0	-28	36		

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

Table 6.04
 Summary of HIVTSQs - Total Treatment Satisfaction Score
 by Visit (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup	Category	Treatment	N	Actual Relative Time	n	Mean	SD	Median	Q1	Q3	Min.	Max.
Region	Rest of World	Q8W	44	Baseline	44	59.3	8.96	63.0	55.5	66.0	22	66
				Week 24	41	61.9	5.65	64.0	61.0	66.0	43	66
				Week 48	40	62.6	6.45	65.5	61.5	66.0	34	66
				W48 CFB	40	3.7	9.11	1.0	0.0	4.5	-18	44
	Q4W	37	Baseline	37	55.3	10.41	58.0	50.0	64.0	20	66	
			Week 24	36	60.4	7.48	64.0	57.0	66.0	36	66	
			Week 48	35	59.3	8.39	63.0	55.0	66.0	37	66	
			W48 CFB	35	4.0	11.03	1.0	0.0	8.0	-16	44	

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

Table 6.05

Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 48 - Overall - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Treatment	N	n	Adjusted Mean[1]	S.E	Difference[2] (95% CI)	P-value	Hedges'g		
							Hedges'g (S.E)	95% CI	P-value
Q8W	327	310	5.01	0.341	1.79 (0.70, 2.89)	0.001	0.3102 (0.08101)	(0.1510, 0.4695)	<.001
Q4W	327	308	3.21	0.440					

[1] Adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, treatment*visit, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

Table 6.06

Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
<35	Q8W	84	80	4.81 (0.676)	1.78 (-0.29, 3.86)	0.092	0.968	0.1613 (0.15310)	(-0.1396, 0.4622)	0.293
	Q4W	98	91	3.03 (0.813)						
35 - <50	Q8W	154	144	4.87 (0.498)	2.00 (0.37, 3.64)	0.017	0.968	0.2341 (0.11986)	(-0.0015, 0.4697)	0.051
	Q4W	143	135	2.87 (0.667)						
>=50	Q8W	89	86	5.44 (0.648)	1.46 (-0.65, 3.56)	0.174	0.968	0.1320 (0.15414)	(-0.1710, 0.4349)	0.392
	Q4W	86	82	3.98 (0.858)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

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Table 6.06

Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
Female	Q8W	73	66	5.21 (0.738)	1.62 (-0.73, 3.97)	0.176	0.807	0.1284 (0.17450)	(-0.2146, 0.4714)	0.462
	Q4W	75	65	3.59 (0.950)						
Male	Q8W	254	244	4.95 (0.385)	1.85 (0.61, 3.09)	0.004	0.807	0.2840 (0.09099)	(0.1051, 0.4628)	0.002
	Q4W	252	243	3.10 (0.499)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

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Table 6.06

Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
White	Q8W	238	226	5.51 (0.400)	2.11 (0.86, 3.36)	0.001	0.798	0.3188 (0.09289)	(0.1362, 0.5014)	<.001
	Q4W	256	243	3.41 (0.497)						
Non-White	Q8W	89	84	3.51 (0.662)	0.84 (-1.44, 3.11)	0.470	0.798	0.0712 (0.16492)	(-0.2529, 0.3954)	0.666
	Q4W	71	65	2.68 (0.955)						

[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

Table 6.06

Statistical Analysis of HIVTSQs - Change from Maintenance Baseline in Total Treatment Satisfaction Score at Week 48 by Subgroup - MMRM - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

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

Category	Treatment	N	n	Adjusted Mean[1] (S.E)	Difference[2] (95% CI)	P-value	Interaction P-value	Hedges'g		
								Hedges'g (S.E)	95% CI	P-value
North America	Q8W	118	113	4.44 (0.582)	0.61 (-1.14, 2.36)	0.496	0.157	0.0654 (0.12912)	(-0.1884, 0.3191)	0.613
	Q4W	135	127	3.83 (0.687)						
Europe	Q8W	165	157	5.34 (0.495)	2.54 (0.97, 4.11)	0.002	0.157	0.3095 (0.11526)	(0.0830, 0.5361)	0.008
	Q4W	155	146	2.80 (0.650)						
Rest of World	Q8W	44	40	5.27 (0.997)	2.54 (-0.65, 5.73)	0.119	0.157	0.1539 (0.23110)	(-0.3003, 0.6082)	0.506
	Q4W	37	35	2.73 (1.325)						

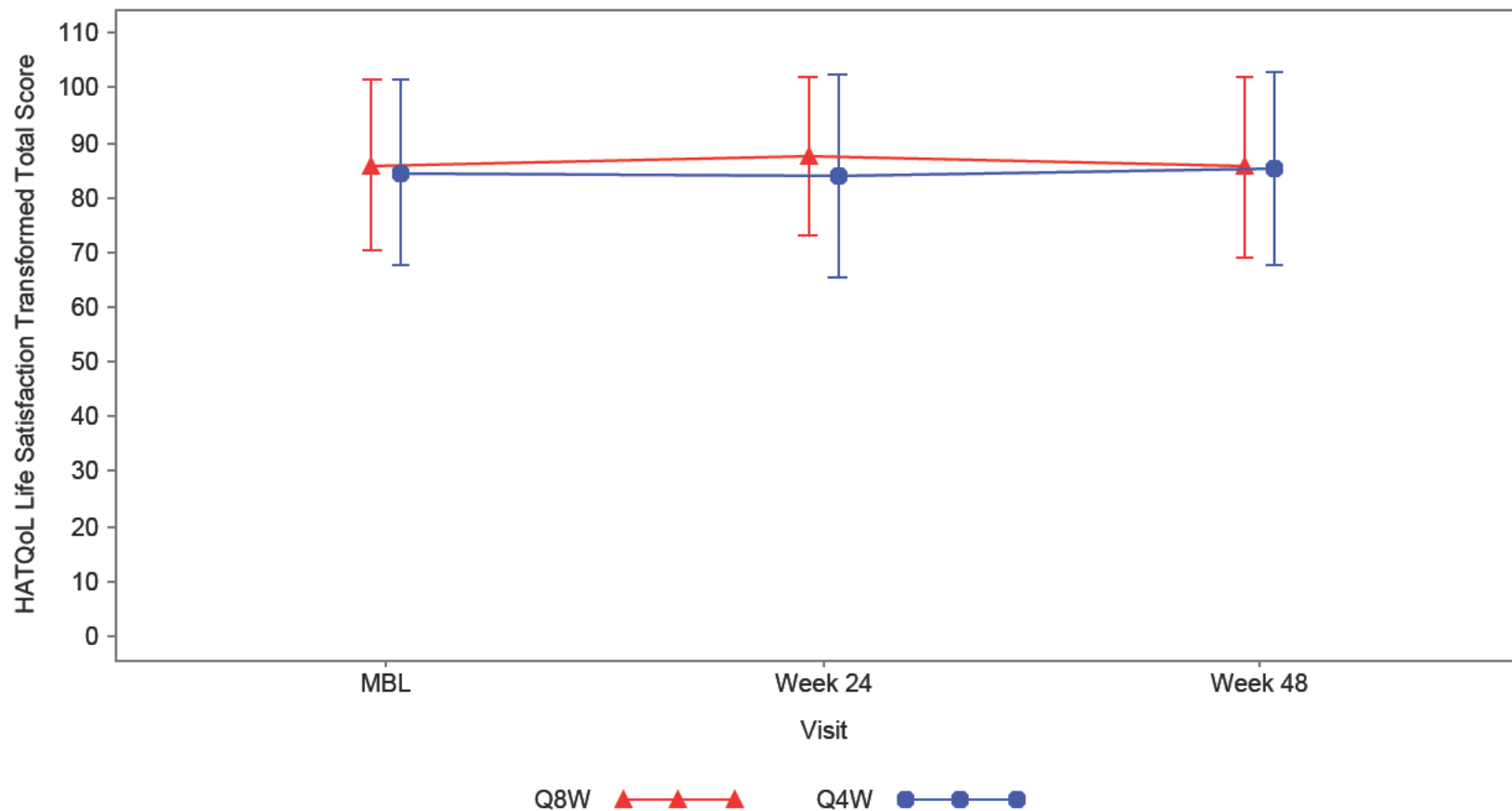
[1] For each subgroup, adjusted mean is the estimated mean change from baseline in each arm calculated from repeated measures model with the following variables: treatment, visit, subgroup, treatment*visit, treatment*subgroup, visit*subgroup, treatment*visit*subgroup, Maintenance Baseline Score, sex at birth (female, male), age (<50, >=50 years; or <35, 35 - <50, >=50 years if subgroup = age), and race (white, non-white), with visit as the repeated factor. No assumptions were made about the correlations between subject readings of HIVTSQs scores i.e. the correlation matrix for within-subject errors is unstructured.

[2] Difference: Q8W - Q4W.

Note: MMRM = Mixed Model Repeated Measures.

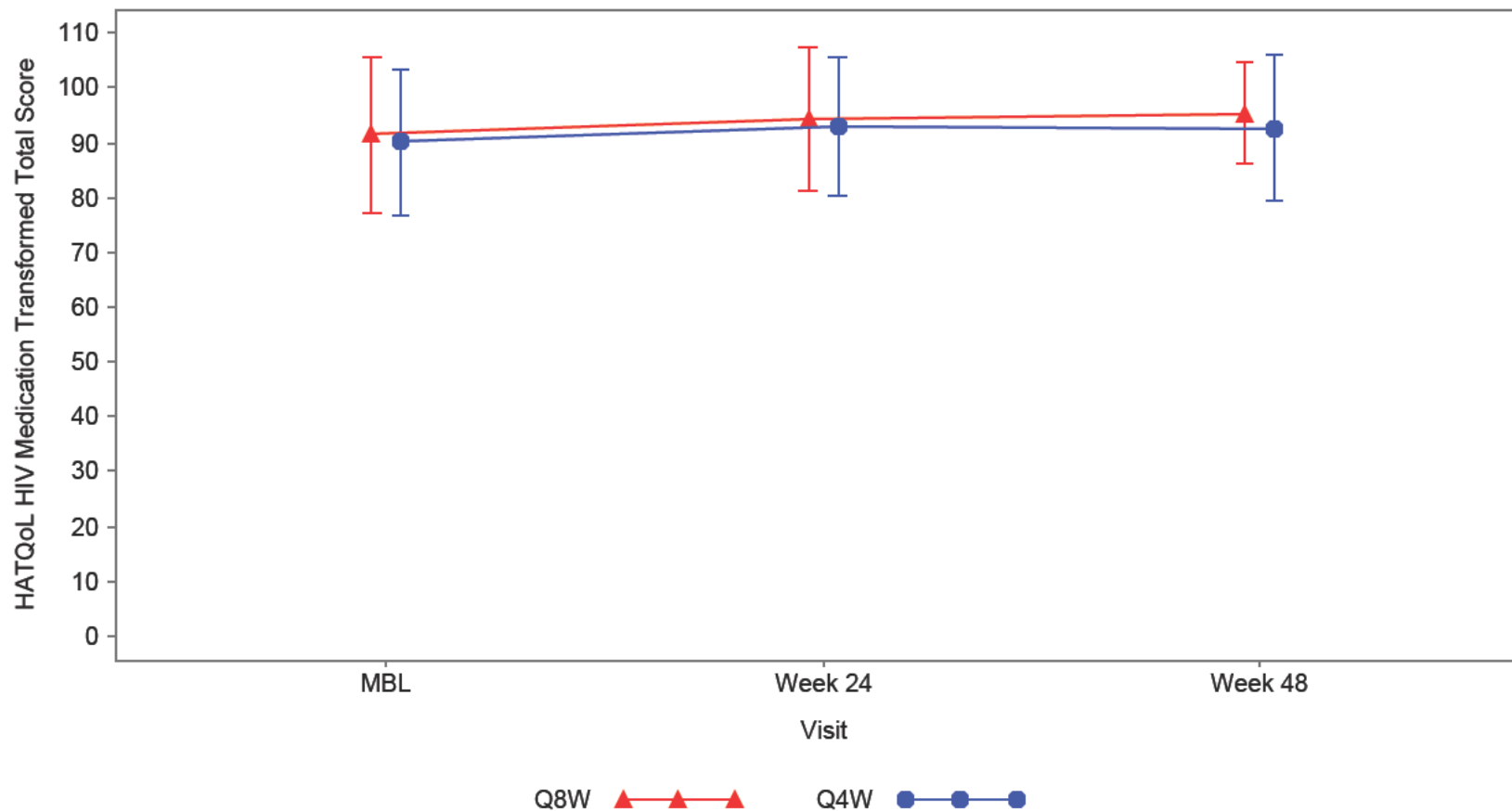
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Figure 6.01
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)



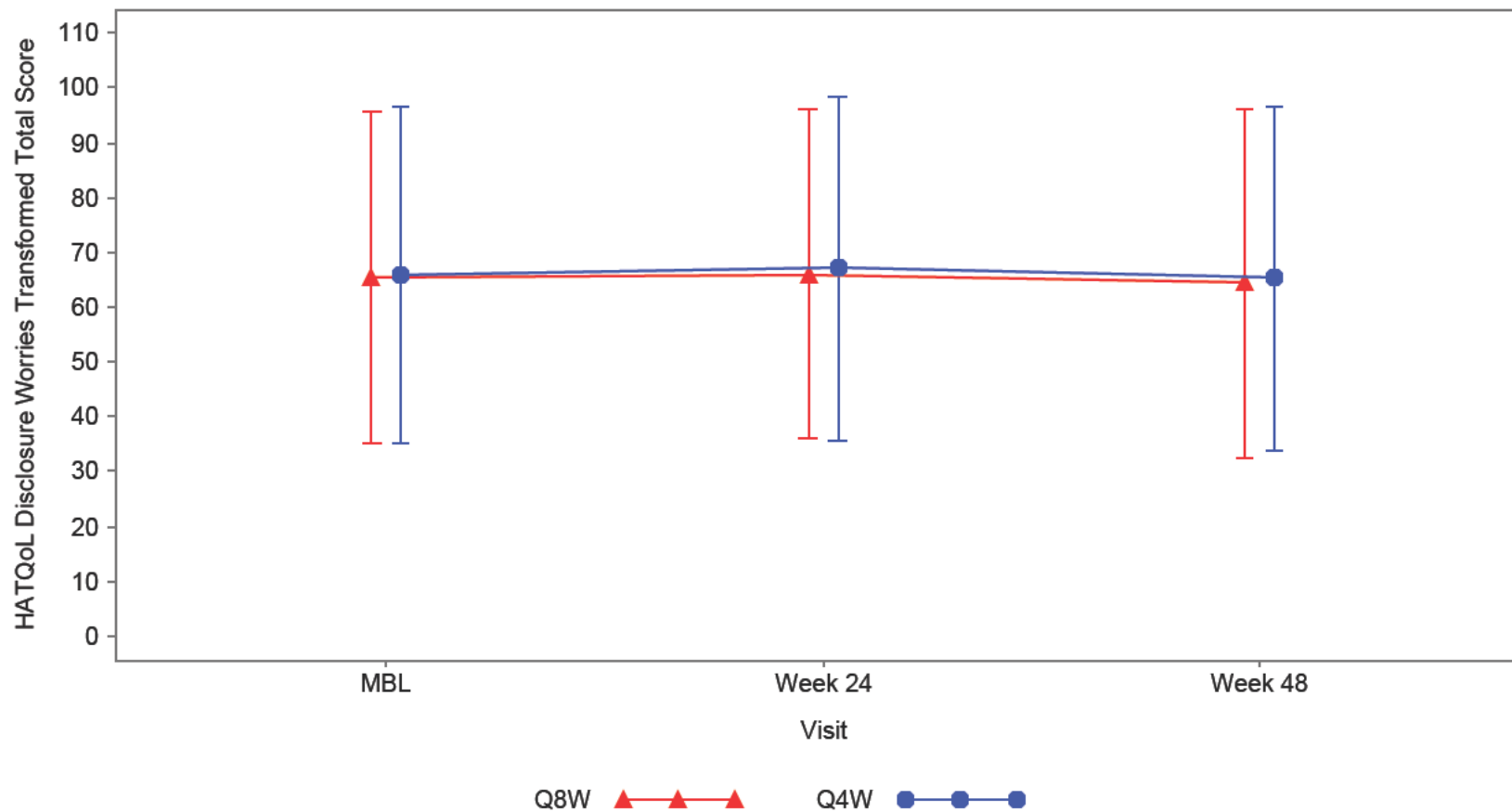
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.01
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)



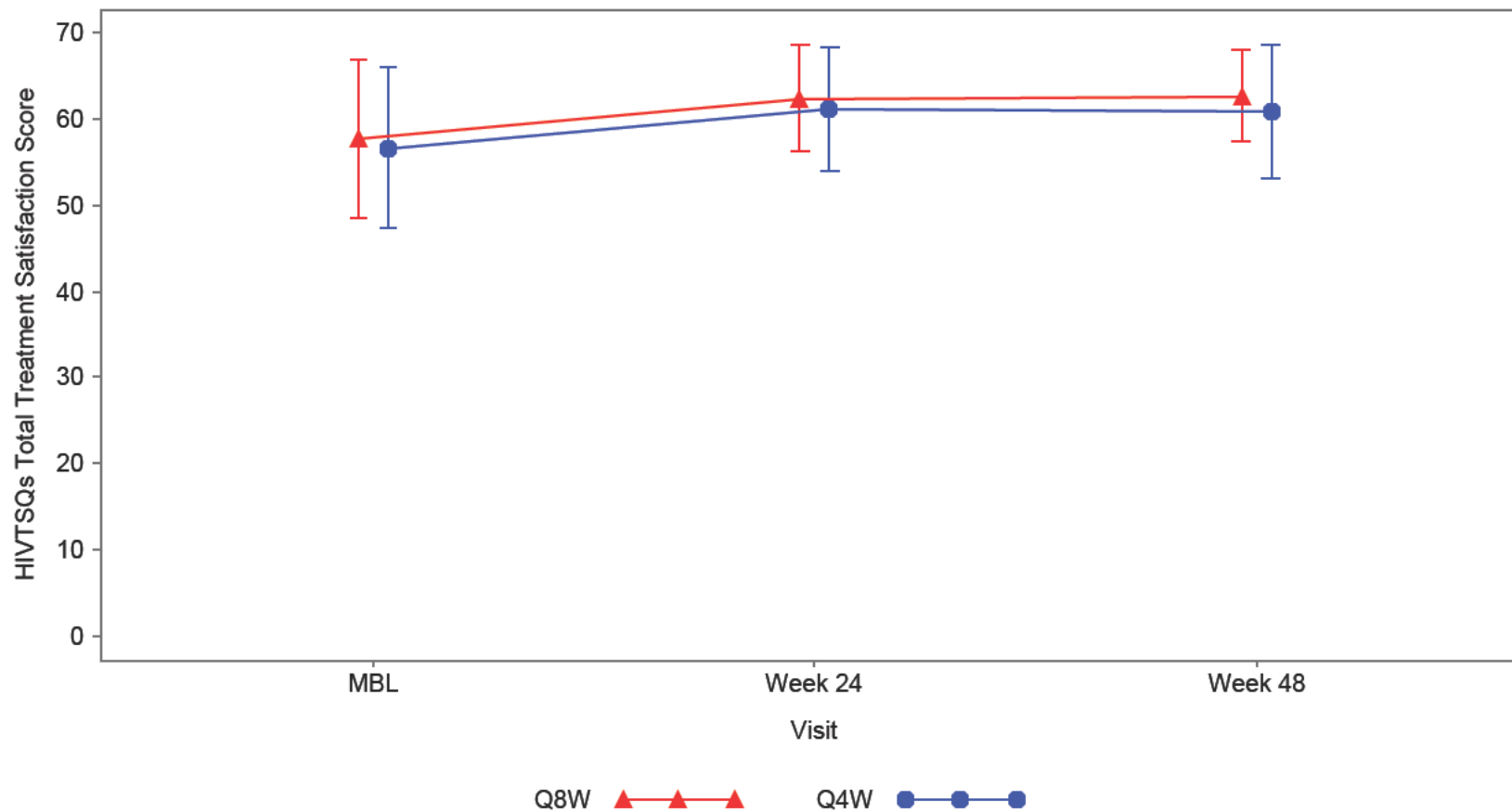
Note: Bars indicate standard deviation (SD). MBL = Maintenance Baseline (Day 1).

Figure 6.01
Line Plot of Quality of Life (HATQoL) - Mean Life Satisfaction, HIV Medication, and
Disclosure Worries Over Time (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)



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

Figure 6.02
Line Plot of HIVTSQs - Mean Total Treatment Satisfaction Score Over Time (Maintenance Phase)
- ATLAS-2M (Prior CAB + RPV of 0 Weeks)



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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	303 (93%)	310 (95%)	0.6923 (0.3646, 1.3145) /0.261	-2.1407 (-5.8527, 1.5713) /0.258	0.9774 (0.9394, 1.0170) /0.259
Max Grade 1	125 (38%)	124 (38%)	1.0131 (0.7388, 1.3891) /0.936	0.3058 (-7.1370, 7.7486) /0.936	1.0081 (0.8291, 1.2257) /0.936
Max Grade 2	156 (48%)	151 (46%)	1.0633 (0.7821, 1.4457) /0.695	1.5291 (-6.1198, 9.1779) /0.695	1.0331 (0.8777, 1.2160) /0.695
Max Grade 3	20 (6%)	33 (10%)	0.5804 (0.3256, 1.0345) /0.065	-3.9755 (-8.1474, 0.1963) /0.062	0.6061 (0.3554, 1.0336) /0.066
Max Grade 4	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

General disorders and administration site conditions					
Any Event	279 (85%)	275 (84%)	1.0991 (0.7177, 1.6832) /0.664	1.2232 (-4.2925, 6.7390) /0.664	1.0145 (0.9506, 1.0828) /0.664
Max Grade 1	165 (50%)	153 (47%)	1.1583 (0.8522, 1.5744) /0.348	3.6697 (-3.9863, 11.3257) /0.347	1.0784 (0.9210, 1.2627) /0.348
Max Grade 2	107 (33%)	104 (32%)	1.0429 (0.7513, 1.4476) /0.802	0.9174 (-6.2479, 8.0827) /0.802	1.0288 (0.8239, 1.2848) /0.802
Max Grade 3	7 (2%)	18 (6%)	0.3755 (0.1547, 0.9116) /0.030	-3.3639 (-6.2916, -0.4362) /0.024	0.3889 (0.1646, 0.9185) /0.031
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site pain					
Any Event	262 (80%)	256 (78%)	1.1179 (0.7660, 1.6314) /0.563	1.8349 (-4.3843, 8.0541) /0.563	1.0234 (0.9461, 1.1071) /0.563
Max Grade 1	157 (48%)	147 (45%)	1.1309 (0.8315, 1.5379) /0.433	3.0581 (-4.5834, 10.6996) /0.433	1.0680 (0.9059, 1.2592) /0.433
Max Grade 2	99 (30%)	92 (28%)	1.1091 (0.7916, 1.5540) /0.547	2.1407 (-4.8272, 9.1085) /0.547	1.0761 (0.8474, 1.3664) /0.547
Max Grade 3	6 (2%)	17 (5%)	0.3408 (0.1327, 0.8758) /0.025	-3.3639 (-6.1756, -0.5522) /0.019	0.3529 (0.1409, 0.8839) /0.026
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site nodule					
Any Event	30 (9%)	62 (19%)	0.4317 (0.2708, 0.6882) /<.001	-9.7859 (-15.0622, -4.5096) /<.001	0.4839 (0.3217, 0.7277) /<.001
Max Grade 1	27 (8%)	47 (14%)	0.5362 (0.3250, 0.8845) /0.015	-6.1162 (-10.9491, -1.2833) /0.013	0.5745 (0.3671, 0.8990) /0.015
Max Grade 2	3 (<1%)	15 (5%)	0.1926 (0.0552, 0.6717) /0.010	-3.6697 (-6.1616, -1.1778) /0.004	0.2000 (0.0585, 0.6843) /0.010
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site discomfort					
Any Event	26 (8%)	29 (9%)	0.8876 (0.5105, 1.5432) /0.673	-0.9174 (-5.1709, 3.3361) /0.672	0.8966 (0.5402, 1.4881) /0.673
Max Grade 1	20 (6%)	25 (8%)	0.7870 (0.4280, 1.4470) /0.441	-1.5291 (-5.4072, 2.3491) /0.440	0.8000 (0.4535, 1.4113) /0.441
Max Grade 2	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 3	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pyrexia					
Any Event	21 (6%)	34 (10%)	0.5914 (0.3354, 1.0427) /0.069	-3.9755 (-8.2187, 0.2676) /0.066	0.6176 (0.3665, 1.0409) /0.070
Max Grade 1	15 (5%)	26 (8%)	0.5566 (0.2891, 1.0714) /0.080	-3.3639 (-7.0706, 0.3428) /0.075	0.5769 (0.3114, 1.0690) /0.080
Max Grade 2	5 (2%)	8 (2%)	0.6192 (0.2004, 1.9130) /0.405	-0.9174 (-3.0558, 1.2209) /0.400	0.6250 (0.2066, 1.8904) /0.405
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site induration					
Any Event	23 (7%)	28 (9%)	0.8079 (0.4550, 1.4346) /0.467	-1.5291 (-5.6375, 2.5794) /0.466	0.8214 (0.4836, 1.3953) /0.467
Max Grade 1	19 (6%)	25 (8%)	0.7452 (0.4020, 1.3815) /0.350	-1.8349 (-5.6720, 2.0023) /0.349	0.7600 (0.4270, 1.3526) /0.351
Max Grade 2	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site swelling					
Any Event	23 (7%)	19 (6%)	1.2265 (0.6545, 2.2981) /0.524	1.2232 (-2.5332, 4.9797) /0.523	1.2105 (0.6724, 2.1793) /0.524
Max Grade 1	14 (4%)	13 (4%)	1.0804 (0.4997, 2.3356) /0.844	0.3058 (-2.7436, 3.3552) /0.844	1.0769 (0.5142, 2.2553) /0.844
Max Grade 2	8 (2%)	6 (2%)	1.3417 (0.4603, 3.9107) /0.590	0.6116 (-1.6064, 2.8297) /0.589	1.3333 (0.4678, 3.8001) /0.590
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fatigue					
Any Event	8 (2%)	24 (7%)	0.3166 (0.1401, 0.7156) /0.006	-4.8930 (-8.1782, -1.6077) /0.004	0.3333 (0.1520, 0.7310) /0.006
Max Grade 1	6 (2%)	19 (6%)	0.3030 (0.1194, 0.7688) /0.012	-3.9755 (-6.8987, -1.0523) /0.008	0.3158 (0.1278, 0.7806) /0.013
Max Grade 2	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site pruritus					
Any Event	8 (2%)	16 (5%)	0.4875 (0.2057, 1.1553) /0.103	-2.4465 (-5.3223, 0.4294) /0.095	0.5000 (0.2170, 1.1521) /0.104
Max Grade 1	6 (2%)	15 (5%)	0.3888 (0.1489, 1.0149) /0.054	-2.7523 (-5.4463, -0.0583) /0.045	0.4000 (0.1572, 1.0181) /0.055
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Asthenia					
Any Event	14 (4%)	7 (2%)	2.0447 (0.8144, 5.1337) /0.128	2.1407 (-0.5566, 4.8379) /0.120	2.0000 (0.8178, 4.8910) /0.129
Max Grade 1	11 (3%)	6 (2%)	1.8623 (0.6805, 5.0968) /0.226	1.5291 (-0.9071, 3.9652) /0.219	1.8333 (0.6861, 4.8987) /0.227
Max Grade 2	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site erythema					
Any Event	9 (3%)	12 (4%)	0.7429 (0.3087, 1.7879) /0.507	-0.9174 (-3.6188, 1.7839) /0.506	0.7500 (0.3204, 1.7557) /0.507
Max Grade 1	9 (3%)	11 (3%)	0.8130 (0.3323, 1.9890) /0.650	-0.6116 (-3.2504, 2.0272) /0.650	0.8182 (0.3436, 1.9481) /0.650
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chills					
Any Event	12 (4%)	8 (2%)	1.5190 (0.6127, 3.7664) /0.367	1.2232 (-1.4143, 3.8608) /0.363	1.5000 (0.6213, 3.6213) /0.367
Max Grade 1	10 (3%)	7 (2%)	1.4421 (0.5422, 3.8358) /0.463	0.9174 (-1.5205, 3.3554) /0.461	1.4286 (0.5505, 3.7073) /0.464
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza like illness					
Any Event	5 (2%)	12 (4%)	0.4076 (0.1420, 1.1704) /0.095	-2.1407 (-4.5741, 0.2928) /0.085	0.4167 (0.1485, 1.1694) /0.096
Max Grade 1	4 (1%)	11 (3%)	0.3558 (0.1121, 1.1290) /0.079	-2.1407 (-4.4294, 0.1481) /0.067	0.3636 (0.1170, 1.1303) /0.080
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site bruising					
Any Event	8 (2%)	9 (3%)	0.8861 (0.3376, 2.3257) /0.806	-0.3058 (-2.7447, 2.1330) /0.806	0.8889 (0.3472, 2.2754) /0.806
Max Grade 1	8 (2%)	6 (2%)	1.3417 (0.4603, 3.9107) /0.590	0.6116 (-1.6064, 2.8297) /0.589	1.3333 (0.4678, 3.8001) /0.590
Max Grade 2	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Malaise					
Any Event	6 (2%)	7 (2%)	0.8545 (0.2840, 2.5705) /0.780	-0.3058 (-2.4452, 1.8336) /0.779	0.8571 (0.2912, 2.5230) /0.780
Max Grade 1	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site warmth					
Any Event	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain					
Any Event	3 (<1%)	8 (2%)	0.3692 (0.0971, 1.4042) /0.144	-1.5291 (-3.4967, 0.4386) /0.128	0.3750 (0.1004, 1.4010) /0.145
Max Grade 1	2 (<1%)	7 (2%)	0.2813 (0.0580, 1.3645) /0.115	-1.5291 (-3.3109, 0.2528) /0.093	0.2857 (0.0598, 1.3651) /0.116
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site haematoma					
Any Event	1 (<1%)	9 (3%)	0.1084 (0.0137, 0.8604) /0.036	-2.4465 (-4.3180, -0.5750) /0.010	0.1111 (0.0142, 0.8720) /0.037
Max Grade 1	0	8 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chest pain					
Any Event	4 (1%)	4 (1%)	1.0000 (0.2480, 4.0328) />0.999	<0.0001 (-1.6849, 1.6849) />0.999	1.0000 (0.2522, 3.9646) />0.999
Max Grade 1	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Discomfort					
Any Event	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Max Grade 1	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site reaction					
Any Event	3 (<1%)	2 (<1%)	1.5046 (0.2498, 9.0643) /0.656	0.3058 (-1.0291, 1.6407) /0.653	1.5000 (0.2523, 8.9181) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Feeling hot					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site anaesthesia					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nodule					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral swelling					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vessel puncture site haematoma					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chest discomfort					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gait disturbance					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site discolouration					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site papule					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Non-cardiac chest pain Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chronic fatigue syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Induration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Inflammation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injection site discharge					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site fibrosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site hypersensitivity					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site necrosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site rash					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mass					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oedema peripheral Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sensation of foreign body Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Sluggishness Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Temperature regulation disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Thirst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Xerosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infections and infestations					
Any Event	176 (54%)	201 (61%)	0.7307 (0.5352, 0.9974) /0.048	-7.6453 (-15.1965, -0.0940) /0.047	0.8756 (0.7673, 0.9993) /0.049
Max Grade 1	105 (32%)	120 (37%)	0.8159 (0.5906, 1.1272) /0.217	-4.5872 (-11.8603, 2.6860) /0.216	0.8750 (0.7076, 1.0820) /0.218
Max Grade 2	66 (20%)	76 (23%)	0.8351 (0.5754, 1.2121) /0.343	-3.0581 (-9.3734, 3.2572) /0.343	0.8684 (0.6485, 1.1629) /0.344
Max Grade 3	4 (1%)	4 (1%)	1.0000 (0.2480, 4.0328) />0.999	<0.0001 (-1.6849, 1.6849) />0.999	1.0000 (0.2522, 3.9646) />0.999
Max Grade 4	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasopharyngitis					
Any Event	48 (15%)	49 (15%)	0.9761 (0.6341, 1.5024) /0.912	-0.3058 (-5.7536, 5.1420) /0.912	0.9796 (0.6784, 1.4144) /0.912
Max Grade 1	35 (11%)	41 (13%)	0.8361 (0.5176, 1.3507) /0.465	-1.8349 (-6.7451, 3.0754) /0.464	0.8537 (0.5585, 1.3047) /0.465
Max Grade 2	13 (4%)	8 (2%)	1.6509 (0.6750, 4.0378) /0.272	1.5291 (-1.1706, 4.2287) /0.267	1.6250 (0.6826, 3.8682) /0.273
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Upper respiratory tract infection					
Any Event	35 (11%)	53 (16%)	0.6197 (0.3921, 0.9793) /0.040	-5.5046 (-10.7183, -0.2909) /0.039	0.6604 (0.4434, 0.9836) /0.041
Max Grade 1	24 (7%)	38 (12%)	0.6024 (0.3525, 1.0294) /0.064	-4.2813 (-8.7596, 0.1969) /0.061	0.6316 (0.3879, 1.0284) /0.065
Max Grade 2	11 (3%)	15 (5%)	0.7241 (0.3274, 1.6011) /0.425	-1.2232 (-4.2166, 1.7702) /0.423	0.7333 (0.3420, 1.5724) /0.425
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastroenteritis					
Any Event	11 (3%)	23 (7%)	0.4601 (0.2205, 0.9601) /0.039	-3.6697 (-7.0610, -0.2785) /0.034	0.4783 (0.2370, 0.9650) /0.039
Max Grade 1	9 (3%)	14 (4%)	0.6327 (0.2700, 1.4831) /0.292	-1.5291 (-4.3501, 1.2920) /0.288	0.6429 (0.2822, 1.4643) /0.293
Max Grade 2	2 (<1%)	9 (3%)	0.2174 (0.0466, 1.0142) /0.052	-2.1407 (-4.1050, -0.1764) /0.033	0.2222 (0.0484, 1.0206) /0.053
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis					
Any Event	11 (3%)	18 (6%)	0.5976 (0.2777, 1.2859) /0.188	-2.1407 (-5.2918, 1.0104) /0.183	0.6111 (0.2932, 1.2735) /0.189
Max Grade 1	7 (2%)	12 (4%)	0.5742 (0.2232, 1.4774) /0.250	-1.5291 (-4.1008, 1.0427) /0.244	0.5833 (0.2326, 1.4630) /0.251
Max Grade 2	4 (1%)	6 (2%)	0.6625 (0.1852, 2.3700) /0.527	-0.6116 (-2.4919, 1.2686) /0.524	0.6667 (0.1899, 2.3405) /0.527
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Syphilis					
Any Event	7 (2%)	16 (5%)	0.4252 (0.1726, 1.0477) /0.063	-2.7523 (-5.5679, 0.0633) /0.055	0.4375 (0.1824, 1.0494) /0.064
Max Grade 1	5 (2%)	10 (3%)	0.4922 (0.1664, 1.4562) /0.200	-1.5291 (-3.8207, 0.7626) /0.191	0.5000 (0.1728, 1.4468) /0.201
Max Grade 2	2 (<1%)	6 (2%)	0.3292 (0.0660, 1.6433) /0.176	-1.2232 (-2.9055, 0.4590) /0.154	0.3333 (0.0678, 1.6394) /0.176
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bronchitis					
Any Event	11 (3%)	11 (3%)	1.0000 (0.4273, 2.3400) />0.999	<0.0001 (-2.7636, 2.7636) />0.999	1.0000 (0.4397, 2.2740) />0.999
Max Grade 1	6 (2%)	8 (2%)	0.7453 (0.2557, 2.1724) /0.590	-0.6116 (-2.8297, 1.6064) /0.589	0.7500 (0.2632, 2.1376) /0.590
Max Grade 2	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Influenza					
Any Event	9 (3%)	11 (3%)	0.8130 (0.3323, 1.9890) /0.650	-0.6116 (-3.2504, 2.0272) /0.650	0.8182 (0.3436, 1.9481) /0.650
Max Grade 1	6 (2%)	6 (2%)	1.0000 (0.3191, 3.1334) />0.999	<0.0001 (-2.0572, 2.0572) />0.999	1.0000 (0.3259, 3.0684) />0.999
Max Grade 2	3 (<1%)	5 (2%)	0.5963 (0.1413, 2.5159) /0.482	-0.6116 (-2.2959, 1.0726) /0.477	0.6000 (0.1446, 2.4900) /0.482
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gonorrhoea					
Any Event	9 (3%)	9 (3%)	1.0000 (0.3918, 2.5521) />0.999	<0.0001 (-2.5077, 2.5077) />0.999	1.0000 (0.4021, 2.4871) />0.999
Max Grade 1	8 (2%)	6 (2%)	1.3417 (0.4603, 3.9107) /0.590	0.6116 (-1.6064, 2.8297) /0.589	1.3333 (0.4678, 3.8001) /0.590
Max Grade 2	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sinusitis					
Any Event	7 (2%)	9 (3%)	0.7729 (0.2844, 2.1007) /0.614	-0.6116 (-2.9792, 1.7559) /0.613	0.7778 (0.2931, 2.0636) /0.614
Max Grade 1	5 (2%)	7 (2%)	0.7099 (0.2230, 2.2599) /0.562	-0.6116 (-2.6683, 1.4450) /0.560	0.7143 (0.2290, 2.2275) /0.562
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory tract infection viral					
Any Event	6 (2%)	8 (2%)	0.7453 (0.2557, 2.1724) /0.590	-0.6116 (-2.8297, 1.6064) /0.589	0.7500 (0.2632, 2.1376) /0.590
Max Grade 1	4 (1%)	6 (2%)	0.6625 (0.1852, 2.3700) /0.527	-0.6116 (-2.4919, 1.2686) /0.524	0.6667 (0.1899, 2.3405) /0.527
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chlamydial infection					
Any Event	8 (2%)	5 (2%)	1.6150 (0.5227, 4.9898) /0.405	0.9174 (-1.2209, 3.0558) /0.400	1.6000 (0.5290, 4.8394) /0.405
Max Grade 1	6 (2%)	4 (1%)	1.5093 (0.4219, 5.3990) /0.527	0.6116 (-1.2686, 2.4919) /0.524	1.5000 (0.4273, 5.2661) /0.527
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urinary tract infection					
Any Event	4 (1%)	9 (3%)	0.4376 (0.1334, 1.4353) /0.173	-1.5291 (-3.6653, 0.6072) /0.161	0.4444 (0.1382, 1.4288) /0.173
Max Grade 1	3 (<1%)	5 (2%)	0.5963 (0.1413, 2.5159) /0.482	-0.6116 (-2.2959, 1.0726) /0.477	0.6000 (0.1446, 2.4900) /0.482
Max Grade 2	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral infection					
Any Event	7 (2%)	6 (2%)	1.1703 (0.3890, 3.5206) /0.780	0.3058 (-1.8336, 2.4452) /0.779	1.1667 (0.3964, 3.4341) /0.780
Max Grade 1	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis gonococcal Any Event	4 (1%)	8 (2%)	0.4938 (0.1472, 1.6562) /0.253	-1.2232 (-3.2783, 0.8318) /0.243	0.5000 (0.1520, 1.6442) /0.254
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	2 (<1%)	6 (2%)	0.3292 (0.0660, 1.6433) /0.176	-1.2232 (-2.9055, 0.4590) /0.154	0.3333 (0.0678, 1.6394) /0.176
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory tract infection Any Event	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 1	5 (2%)	5 (2%)	1.0000 (0.2867, 3.4875) />0.999	<0.0001 (-1.8809, 1.8809) />0.999	1.0000 (0.2923, 3.4215) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tonsillitis					
Any Event	4 (1%)	7 (2%)	0.5661 (0.1641, 1.9527) /0.368	-0.9174 (-2.8873, 1.0524) /0.361	0.5714 (0.1689, 1.9334) /0.368
Max Grade 1	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 2	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Conjunctivitis					
Any Event	3 (<1%)	7 (2%)	0.4233 (0.1085, 1.6513) /0.216	-1.2232 (-3.1018, 0.6553) /0.202	0.4286 (0.1118, 1.6429) /0.217
Max Grade 1	2 (<1%)	6 (2%)	0.3292 (0.0660, 1.6433) /0.176	-1.2232 (-2.9055, 0.4590) /0.154	0.3333 (0.0678, 1.6394) /0.176
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal chlamydia infection					
Any Event	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oral herpes Any Event	2 (<1%)	7 (2%)	0.2813 (0.0580, 1.3645) /0.115	-1.5291 (-3.3109, 0.2528) /0.093	0.2857 (0.0598, 1.3651) /0.116
Max Grade 1	1 (<1%)	6 (2%)	0.1641 (0.0196, 1.3708) /0.095	-1.5291 (-3.1020, 0.0439) /0.057	0.1667 (0.0202, 1.3767) /0.096
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinitis					
Any Event	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 1	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis					
Any Event	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 1	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral upper respiratory tract infection					
Any Event	2 (<1%)	7 (2%)	0.2813 (0.0580, 1.3645) /0.115	-1.5291 (-3.3109, 0.2528) /0.093	0.2857 (0.0598, 1.3651) /0.116
Max Grade 1	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Folliculitis					
Any Event	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 1	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroenteritis viral					
Any Event	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Herpes zoster Any Event	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea versicolour					
Any Event	1 (<1%)	5 (2%)	0.1975 (0.0230, 1.7002) /0.140	-1.2232 (-2.6816, 0.2352) /0.100	0.2000 (0.0235, 1.7025) /0.141
Max Grade 1	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear infection					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fungal skin infection					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Furuncle					
Any Event	3 (<1%)	2 (<1%)	1.5046 (0.2498, 9.0643) /0.656	0.3058 (-1.0291, 1.6407) /0.653	1.5000 (0.2523, 8.9181) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Herpes simplex					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hordeolum					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lower respiratory tract infection					
Any Event	4 (1%)	1 (<1%)	4.0372 (0.4488, 36.3154) /0.213	0.9174 (-0.4158, 2.2507) /0.177	4.0000 (0.4495, 35.5960) /0.214
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oropharyngeal gonococcal infection					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pneumonia					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth abscess Any Event	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis gonococcal Any Event	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gingivitis					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Mycoplasma genitalium infection					
Any Event	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Onychomycosis					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tooth infection					
Any Event	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acarodermatitis					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Body tinea					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cellulitis					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diverticulitis					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Genital herpes					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oral candidiasis					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Otitis externa					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Paronychia					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngotonsillitis					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Secondary syphilis					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tracheitis					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethritis chlamydial Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vaginal infection					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral pharyngitis Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute hepatitis B					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cystitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Enteritis infectious					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epididymitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Escherichia urinary tract infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Helicobacter infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hepatitis E					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection site abscess					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Laryngitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lymphogranuloma venereum					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Molluscum contagiosum					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Orchitis					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Otitis media					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngeal chlamydia infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis streptococcal Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Postoperative wound infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Primary syphilis Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Pulpitis dental					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Shigella infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Skin infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Staphylococcal infection					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Staphylococcal skin infection					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ureaplasma infection					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Varicella					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abscess limb					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anal abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Arthropod infestation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Asymptomatic bacteriuria					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Bacterial diarrhoea					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Bacterial vaginosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bronchitis viral					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Candida infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chest wall abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chronic sinusitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cutaneous blastomycosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diarrhoea infectious Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Enterovirus infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Epiglottitis obstructive Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 5	0	0			
Erysipelas Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Erythema migrans					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Escherichia infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

External ear cellulitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gastritis viral					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastroenteritis					
Escherichia coli					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Genital candidiasis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Genital herpes simplex					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Groin abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infectious mononucleosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Labyrinthitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Lice infestation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mycoplasma infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Oesophageal candidiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ophthalmic herpes zoster Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Otitis media acute					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Penile infection					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Pericoronitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Perirectal abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peritonsillar abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis bacterial					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pharyngitis mycoplasmal Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis chlamydial Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Proctitis mycoplasmal Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pulmonary tuberculosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rectal abscess					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subcutaneous abscess					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Syphilis genital					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinea capitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tinea cruris					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Tinea pedis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tracheobronchitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Trichomoniasis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Viral rash Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Viral rhinitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vulvovaginal mycotic infection					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Gastrointestinal disorders					
Any Event	71 (22%)	93 (28%)	0.6978 (0.4887, 0.9964) /0.048	-6.7278 (-13.3518, -0.1038) /0.047	0.7634 (0.5839, 0.9983) /0.049
Max Grade 1	52 (16%)	66 (20%)	0.7478 (0.5008, 1.1166) /0.155	-4.2813 (-10.1665, 1.6038) /0.154	0.7879 (0.5667, 1.0954) /0.156
Max Grade 2	17 (5%)	26 (8%)	0.6349 (0.3376, 1.1939) /0.159	-2.7523 (-6.5454, 1.0408) /0.155	0.6538 (0.3618, 1.1817) /0.159
Max Grade 3	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diarrhoea					
Any Event	25 (8%)	24 (7%)	1.0451 (0.5838, 1.8710) /0.882	0.3058 (-3.7295, 4.3411) /0.882	1.0417 (0.6078, 1.7852) /0.882
Max Grade 1	20 (6%)	18 (6%)	1.1183 (0.5803, 2.1553) /0.738	0.6116 (-2.9739, 4.1972) /0.738	1.1111 (0.5989, 2.0615) /0.738
Max Grade 2	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nausea					
Any Event	8 (2%)	20 (6%)	0.3850 (0.1671, 0.8870) /0.025	-3.6697 (-6.7599, -0.5795) /0.020	0.4000 (0.1788, 0.8951) /0.026
Max Grade 1	5 (2%)	17 (5%)	0.2832 (0.1032, 0.7769) /0.014	-3.6697 (-6.4190, -0.9204) /0.009	0.2941 (0.1098, 0.7878) /0.015
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dyspepsia					
Any Event	6 (2%)	8 (2%)	0.7453 (0.2557, 2.1724) /0.590	-0.6116 (-2.8297, 1.6064) /0.589	0.7500 (0.2632, 2.1376) /0.590
Max Grade 1	6 (2%)	7 (2%)	0.8545 (0.2840, 2.5705) /0.780	-0.3058 (-2.4452, 1.8336) /0.779	0.8571 (0.2912, 2.5230) /0.780
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal pain					
Any Event	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 1	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoids					
Any Event	3 (<1%)	8 (2%)	0.3692 (0.0971, 1.4042) /0.144	-1.5291 (-3.4967, 0.4386) /0.128	0.3750 (0.1004, 1.4010) /0.145
Max Grade 1	1 (<1%)	7 (2%)	0.1402 (0.0172, 1.1462) /0.067	-1.8349 (-3.5139, -0.1558) /0.032	0.1429 (0.0177, 1.1546) /0.068
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Toothache					
Any Event	4 (1%)	7 (2%)	0.5661 (0.1641, 1.9527) /0.368	-0.9174 (-2.8873, 1.0524) /0.361	0.5714 (0.1689, 1.9334) /0.368
Max Grade 1	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 2	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastroesophageal reflux disease					
Any Event	3 (<1%)	6 (2%)	0.4954 (0.1228, 1.9978) /0.323	-0.9174 (-2.7018, 0.8669) /0.314	0.5000 (0.1261, 1.9823) /0.324
Max Grade 1	3 (<1%)	2 (<1%)	1.5046 (0.2498, 9.0643) /0.656	0.3058 (-1.0291, 1.6407) /0.653	1.5000 (0.2523, 8.9181) /0.656
Max Grade 2	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vomiting					
Any Event	6 (2%)	3 (<1%)	2.0187 (0.5006, 8.1411) /0.323	0.9174 (-0.8669, 2.7018) /0.314	2.0000 (0.5045, 7.9292) /0.324
Max Grade 1	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal distension					
Any Event	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 1	4 (1%)	2 (<1%)	2.0124 (0.3660, 11.0637) /0.421	0.6116 (-0.8490, 2.0723) /0.412	2.0000 (0.3689, 10.8438) /0.422
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Constipation					
Any Event	1 (<1%)	7 (2%)	0.1402 (0.0172, 1.1462) /0.067	-1.8349 (-3.5139, -0.1558) /0.032	0.1429 (0.0177, 1.1546) /0.068
Max Grade 1	0	7 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal pain upper					
Any Event	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 1	3 (<1%)	2 (<1%)	1.5046 (0.2498, 9.0643) /0.656	0.3058 (-1.0291, 1.6407) /0.653	1.5000 (0.2523, 8.9181) /0.656
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abdominal discomfort					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anogenital dysplasia					
Any Event	3 (<1%)	2 (<1%)	1.5046 (0.2498, 9.0643) /0.656	0.3058 (-1.0291, 1.6407) /0.653	1.5000 (0.2523, 8.9181) /0.656
Max Grade 1	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal pain lower					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gastritis					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anal fistula					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Flatulence					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Inguinal hernia					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Colitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dry mouth					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Gingival pain					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Irritable bowel syndrome					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Noninfective gingivitis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rectal discharge					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rectal haemorrhage Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Abdominal hernia Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abdominal tenderness					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Anal fissure					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal pruritus					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Angular cheilitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cheilitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Crohn's disease					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Dental caries Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Enterocolitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Food poisoning Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Gastric disorder Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gingival hypertrophy Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Haematemesis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Haematochezia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoidal haemorrhage Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Haemorrhoids thrombosed					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hiatus hernia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypertrophic anal papilla Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypoaesthesia oral					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Intestinal polyp					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Large intestine polyp					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mouth ulceration					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Oesophagitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Oroantral fistula					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Pancreatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Perianal erythema					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tooth disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal and connective tissue disorders					
Any Event	65 (20%)	79 (24%)	0.7788 (0.5372, 1.1290) /0.187	-4.2813 (-10.6244, 2.0617) /0.186	0.8228 (0.6155, 1.0998) /0.188
Max Grade 1	41 (13%)	53 (16%)	0.7411 (0.4773, 1.1508) /0.182	-3.6697 (-9.0397, 1.7003) /0.180	0.7736 (0.5302, 1.1286) /0.183
Max Grade 2	20 (6%)	23 (7%)	0.8611 (0.4633, 1.6005) /0.636	-0.9174 (-4.7158, 2.8809) /0.636	0.8696 (0.4872, 1.5520) /0.636
Max Grade 3	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Back pain					
Any Event	16 (5%)	20 (6%)	0.7897 (0.4017, 1.5526) /0.494	-1.2232 (-4.7179, 2.2714) /0.493	0.8000 (0.4221, 1.5161) /0.494
Max Grade 1	13 (4%)	17 (5%)	0.7550 (0.3606, 1.5807) /0.456	-1.2232 (-4.4286, 1.9821) /0.454	0.7647 (0.3776, 1.5487) /0.456
Max Grade 2	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthralgia					
Any Event	16 (5%)	16 (5%)	1.0000 (0.4914, 2.0351) />0.999	<0.0001 (-3.3066, 3.3066) />0.999	1.0000 (0.5088, 1.9656) />0.999
Max Grade 1	10 (3%)	11 (3%)	0.9062 (0.3795, 2.1640) /0.825	-0.3058 (-3.0079, 2.3963) /0.824	0.9091 (0.3915, 2.1111) /0.825
Max Grade 2	6 (2%)	4 (1%)	1.5093 (0.4219, 5.3990) /0.527	0.6116 (-1.2686, 2.4919) /0.524	1.5000 (0.4273, 5.2661) /0.527
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain in extremity					
Any Event	8 (2%)	13 (4%)	0.6057 (0.2477, 1.4816) /0.272	-1.5291 (-4.2287, 1.1706) /0.267	0.6154 (0.2585, 1.4649) /0.273
Max Grade 1	7 (2%)	10 (3%)	0.6934 (0.2607, 1.8445) /0.463	-0.9174 (-3.3554, 1.5205) /0.461	0.7000 (0.2697, 1.8166) /0.464
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Myalgia					
Any Event	9 (3%)	7 (2%)	1.2938 (0.4760, 3.5164) /0.614	0.6116 (-1.7559, 2.9792) /0.613	1.2857 (0.4846, 3.4112) /0.614
Max Grade 1	7 (2%)	4 (1%)	1.7664 (0.5121, 6.0928) /0.368	0.9174 (-1.0524, 2.8873) /0.361	1.7500 (0.5172, 5.9209) /0.368
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal pain					
Any Event	8 (2%)	5 (2%)	1.6150 (0.5227, 4.9898) /0.405	0.9174 (-1.2209, 3.0558) /0.400	1.6000 (0.5290, 4.8394) /0.405
Max Grade 1	3 (<1%)	5 (2%)	0.5963 (0.1413, 2.5159) /0.482	-0.6116 (-2.2959, 1.0726) /0.477	0.6000 (0.1446, 2.4900) /0.482
Max Grade 2	5 (2%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle spasms					
Any Event	1 (<1%)	7 (2%)	0.1402 (0.0172, 1.1462) /0.067	-1.8349 (-3.5139, -0.1558) /0.032	0.1429 (0.0177, 1.1546) /0.068
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Musculoskeletal chest pain Any Event	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neck pain					
Any Event	5 (2%)	2 (<1%)	2.5233 (0.4860, 13.1000) /0.271	0.9174 (-0.6583, 2.4932) /0.254	2.5000 (0.4885, 12.7935) /0.271
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle contracture Any Event	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Intervertebral disc protrusion					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Osteoarthritis					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rotator cuff syndrome					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tendonitis					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Synovial cyst					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bursitis					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Exostosis Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Joint contracture Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Limb discomfort Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscular weakness					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthritis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Arthropathy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cervical spinal stenosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Costochondritis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Femoroacetabular impingement					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Flank pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Groin pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Joint range of motion decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Joint stiffness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Joint swelling					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle tightness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Musculoskeletal discomfort					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Osteonecrosis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Osteopenia Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pain in jaw Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Periarthritis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Plantar fasciitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Scoliosis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Spinal osteoarthritis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Synovitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Temporomandibular joint syndrome Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Tendon disorder Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tenosynovitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Trigger finger					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin and subcutaneous tissue disorders					
Any Event	54 (17%)	64 (20%)	0.8128 (0.5450, 1.2124) /0.310	-3.0581 (-8.9478, 2.8316) /0.309	0.8438 (0.6077, 1.1714) /0.310
Max Grade 1	39 (12%)	49 (15%)	0.7683 (0.4890, 1.2070) /0.253	-3.0581 (-8.2836, 2.1674) /0.251	0.7959 (0.5380, 1.1775) /0.253
Max Grade 2	15 (5%)	15 (5%)	1.0000 (0.4806, 2.0806) />0.999	<0.0001 (-3.2067, 3.2067) />0.999	1.0000 (0.4970, 2.0119) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pruritus					
Any Event	10 (3%)	8 (2%)	1.2579 (0.4901, 3.2285) /0.633	0.6116 (-1.8956, 3.1189) /0.633	1.2500 (0.4997, 3.1271) /0.633
Max Grade 1	8 (2%)	7 (2%)	1.1464 (0.4109, 3.1990) /0.794	0.3058 (-1.9887, 2.6003) /0.794	1.1429 (0.4193, 3.1151) /0.794
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash					
Any Event	7 (2%)	10 (3%)	0.6934 (0.2607, 1.8445) /0.463	-0.9174 (-3.3554, 1.5205) /0.461	0.7000 (0.2697, 1.8166) /0.464
Max Grade 1	6 (2%)	9 (3%)	0.6604 (0.2324, 1.8771) /0.436	-0.9174 (-3.2110, 1.3761) /0.433	0.6667 (0.2400, 1.8517) /0.437
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eczema					
Any Event	4 (1%)	8 (2%)	0.4938 (0.1472, 1.6562) /0.253	-1.2232 (-3.2783, 0.8318) /0.243	0.5000 (0.1520, 1.6442) /0.254
Max Grade 1	3 (<1%)	7 (2%)	0.4233 (0.1085, 1.6513) /0.216	-1.2232 (-3.1018, 0.6553) /0.202	0.4286 (0.1118, 1.6429) /0.217
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Alopecia					
Any Event	6 (2%)	2 (<1%)	3.0374 (0.6085, 15.1608) /0.176	1.2232 (-0.4590, 2.9055) /0.154	3.0000 (0.6100, 14.7546) /0.176
Max Grade 1	6 (2%)	1 (<1%)	6.0935 (0.7295, 50.8979) /0.095	1.5291 (-0.0439, 3.1020) /0.057	6.0000 (0.7264, 49.5611) /0.096
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin lesion					
Any Event	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dermatitis					
Any Event	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acne					
Any Event	1 (<1%)	5 (2%)	0.1975 (0.0230, 1.7002) /0.140	-1.2232 (-2.6816, 0.2352) /0.100	0.2000 (0.0235, 1.7025) /0.141
Max Grade 1	1 (<1%)	5 (2%)	0.1975 (0.0230, 1.7002) /0.140	-1.2232 (-2.6816, 0.2352) /0.100	0.2000 (0.0235, 1.7025) /0.141
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dermal cyst					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hyperhidrosis Any Event	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Night sweats					
Any Event	4 (1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Seborrhoeic dermatitis					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dermatitis contact					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urticaria					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dry skin					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash erythematous Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin exfoliation Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin fissures					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin mass					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Androgenetic alopecia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dermatitis atopic					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Drug eruption					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ecchymosis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eczema asteatotic					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Erythema					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Granuloma annulare					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hand dermatitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Intertrigo					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Keratosis pilaris					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lichen sclerosus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Macule					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Miliaria					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nail bed inflammation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pain of skin					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pigmentation disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pityriasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Pityriasis rosea					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pruritus generalised					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Psoriasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Purpura					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash maculo-papular Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash morbilliform Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rash pruritic Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rash vesicular					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin discolouration					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin hypertrophy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Skin irritation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin swelling					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Solar dermatitis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nervous system disorders					
Any Event	45 (14%)	52 (16%)	0.8439 (0.5477, 1.3002) /0.442	-2.1407 (-7.5860, 3.3047) /0.441	0.8654 (0.5987, 1.2509) /0.442
Max Grade 1	34 (10%)	34 (10%)	1.0000 (0.6052, 1.6523) />0.999	<0.0001 (-4.6786, 4.6786) />0.999	1.0000 (0.6376, 1.5683) />0.999
Max Grade 2	11 (3%)	17 (5%)	0.6348 (0.2926, 1.3770) /0.250	-1.8349 (-4.9346, 1.2649) /0.246	0.6471 (0.3079, 1.3599) /0.251
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Headache					
Any Event	22 (7%)	27 (8%)	0.8015 (0.4465, 1.4387) /0.458	-1.5291 (-5.5628, 2.5047) /0.458	0.8148 (0.4740, 1.4005) /0.459
Max Grade 1	18 (6%)	17 (5%)	1.0623 (0.5374, 2.0995) /0.862	0.3058 (-3.1439, 3.7555) /0.862	1.0588 (0.5556, 2.0179) /0.862
Max Grade 2	4 (1%)	10 (3%)	0.3926 (0.1219, 1.2647) /0.117	-1.8349 (-4.0489, 0.3792) /0.104	0.4000 (0.1267, 1.2625) /0.118
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dizziness					
Any Event	12 (4%)	10 (3%)	1.2076 (0.5143, 2.8355) /0.665	0.6116 (-2.1516, 3.3749) /0.664	1.2000 (0.5258, 2.7385) /0.665
Max Grade 1	10 (3%)	7 (2%)	1.4421 (0.5422, 3.8358) /0.463	0.9174 (-1.5205, 3.3554) /0.461	1.4286 (0.5505, 3.7073) /0.464
Max Grade 2	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Paraesthesia					
Any Event	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 1	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Presyncope					
Any Event	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Migraine					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sciatica					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Somnolence					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Head discomfort					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypoaesthesia					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lethargy					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
-----	-----	-----	-----	-----	-----
Syncope					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tension headache					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Amnesia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Burning sensation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Carpal tunnel syndrome					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cerebral infarction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cervical radiculopathy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Disturbance in attention					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Dysarthria					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

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

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Hypersomnia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
<hr/>					
Hypertonia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle contractions involuntary					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neuropathy peripheral Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Periodic limb movement disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Polyneuropathy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Radiculopathy					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory, thoracic and mediastinal disorders					
Any Event	39 (12%)	55 (17%)	0.6697 (0.4302, 1.0424) /0.076	-4.8930 (-10.2572, 0.4713) /0.074	0.7091 (0.4846, 1.0375) /0.077
Max Grade 1	32 (10%)	39 (12%)	0.8010 (0.4884, 1.3140) /0.380	-2.1407 (-6.9063, 2.6249) /0.379	0.8205 (0.5276, 1.2761) /0.380
Max Grade 2	7 (2%)	15 (5%)	0.4550 (0.1830, 1.1310) /0.090	-2.4465 (-5.2038, 0.3108) /0.082	0.4667 (0.1928, 1.1295) /0.091
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cough					
Any Event	15 (5%)	21 (6%)	0.7005 (0.3545, 1.3843) /0.306	-1.8349 (-5.3279, 1.6582) /0.303	0.7143 (0.3749, 1.3609) /0.306
Max Grade 1	13 (4%)	19 (6%)	0.6711 (0.3258, 1.3826) /0.280	-1.8349 (-5.1385, 1.4687) /0.276	0.6842 (0.3437, 1.3622) /0.280
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal pain					
Any Event	7 (2%)	11 (3%)	0.6284 (0.2405, 1.6417) /0.343	-1.2232 (-3.7292, 1.2827) /0.339	0.6364 (0.2498, 1.6212) /0.343
Max Grade 1	7 (2%)	9 (3%)	0.7729 (0.2844, 2.1007) /0.614	-0.6116 (-2.9792, 1.7559) /0.613	0.7778 (0.2931, 2.0636) /0.614
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinitis allergic					
Any Event	5 (2%)	6 (2%)	0.8307 (0.2510, 2.7495) /0.761	-0.3058 (-2.2768, 1.6652) /0.761	0.8333 (0.2569, 2.7035) /0.761
Max Grade 1	4 (1%)	2 (<1%)	2.0124 (0.3660, 11.0637) /0.421	0.6116 (-0.8490, 2.0723) /0.412	2.0000 (0.3689, 10.8438) /0.422
Max Grade 2	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sinus congestion					
Any Event	3 (<1%)	6 (2%)	0.4954 (0.1228, 1.9978) /0.323	-0.9174 (-2.7018, 0.8669) /0.314	0.5000 (0.1261, 1.9823) /0.324
Max Grade 1	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal congestion					
Any Event	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 1	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Asthma					
Any Event	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 1	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Epistaxis					
Any Event	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sleep apnoea syndrome					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dyspnoea					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Productive cough					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Catarrh					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemoptysis					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Oropharyngeal discomfort					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Rales					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rhinorrhoea					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bronchospasm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Dry throat					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Interstitial lung disease					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal discomfort Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nasal oedema Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nasal septum deviation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Painful respiration					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Pleuritic pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Respiratory disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory tract congestion Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Snoring Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injury, poisoning and procedural complications					
Any Event	31 (9%)	58 (18%)	0.4857 (0.3047, 0.7743) /0.002	-8.2569 (-13.4743, -3.0394) /0.002	0.5345 (0.3553, 0.8039) /0.003
Max Grade 1	16 (5%)	35 (11%)	0.4292 (0.2326, 0.7920) /0.007	-5.8104 (-9.8963, -1.7245) /0.005	0.4571 (0.2582, 0.8094) /0.007
Max Grade 2	13 (4%)	23 (7%)	0.5472 (0.2722, 1.0999) /0.091	-3.0581 (-6.5461, 0.4299) /0.086	0.5652 (0.2914, 1.0964) /0.091
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthropod bite					
Any Event	2 (<1%)	8 (2%)	0.2454 (0.0517, 1.1644) /0.077	-1.8349 (-3.7104, 0.0407) /0.055	0.2500 (0.0535, 1.1684) /0.078
Max Grade 1	2 (<1%)	6 (2%)	0.3292 (0.0660, 1.6433) /0.176	-1.2232 (-2.9055, 0.4590) /0.154	0.3333 (0.0678, 1.6394) /0.176
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Exposure to communicable disease					
Any Event	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Limb injury					
Any Event	6 (2%)	3 (<1%)	2.0187 (0.5006, 8.1411) /0.323	0.9174 (-0.8669, 2.7018) /0.314	2.0000 (0.5045, 7.9292) /0.324
Max Grade 1	5 (2%)	2 (<1%)	2.5233 (0.4860, 13.1000) /0.271	0.9174 (-0.6583, 2.4932) /0.254	2.5000 (0.4885, 12.7935) /0.271
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Contusion					
Any Event	4 (1%)	4 (1%)	1.0000 (0.2480, 4.0328) />0.999	<0.0001 (-1.6849, 1.6849) />0.999	1.0000 (0.2522, 3.9646) />0.999
Max Grade 1	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ligament sprain Any Event	3 (<1%)	5 (2%)	0.5963 (0.1413, 2.5159) /0.482	-0.6116 (-2.2959, 1.0726) /0.477	0.6000 (0.1446, 2.4900) /0.482
Max Grade 1	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin laceration					
Any Event	2 (<1%)	5 (2%)	0.3963 (0.0763, 2.0575) /0.271	-0.9174 (-2.4932, 0.6583) /0.254	0.4000 (0.0782, 2.0470) /0.271
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle strain					
Any Event	0	6 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin abrasion					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Arthropod sting Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rib fracture					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Animal bite					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

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

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Heat stroke Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Joint injury					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Meniscus injury					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Musculoskeletal foreign body Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Road traffic accident					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaccination complication					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

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

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

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Wrist fracture Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Bone contusion Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Burns second degree					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Chemical burns of eye					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Clavicle fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Concussion					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Corneal abrasion Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Epicondylitis Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fall					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Fibula fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Foot fracture Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Head injury Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injection related reaction					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Injury corneal					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Joint dislocation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lip injury					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nail injury Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Overdose Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Procedural pain Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Scapula fracture Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sunburn					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Thermal burn					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Traumatic haematoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ulna fracture					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Psychiatric disorders					
Any Event	35 (11%)	44 (13%)	0.7709 (0.4804, 1.2373) /0.281	-2.7523 (-7.7431, 2.2385) /0.280	0.7955 (0.5244, 1.2066) /0.282
Max Grade 1	20 (6%)	33 (10%)	0.5804 (0.3256, 1.0345) /0.065	-3.9755 (-8.1474, 0.1963) /0.062	0.6061 (0.3554, 1.0336) /0.066
Max Grade 2	15 (5%)	9 (3%)	1.6987 (0.7326, 3.9389) /0.217	1.8349 (-1.0437, 4.7134) /0.212	1.6667 (0.7399, 3.7542) /0.218
Max Grade 3	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Insomnia					
Any Event	11 (3%)	18 (6%)	0.5976 (0.2777, 1.2859) /0.188	-2.1407 (-5.2918, 1.0104) /0.183	0.6111 (0.2932, 1.2735) /0.189
Max Grade 1	6 (2%)	16 (5%)	0.3633 (0.1404, 0.9405) /0.037	-3.0581 (-5.8118, -0.3044) /0.030	0.3750 (0.1486, 0.9463) /0.038
Max Grade 2	5 (2%)	2 (<1%)	2.5233 (0.4860, 13.1000) /0.271	0.9174 (-0.6583, 2.4932) /0.254	2.5000 (0.4885, 12.7935) /0.271
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Anxiety					
Any Event	9 (3%)	7 (2%)	1.2938 (0.4760, 3.5164) /0.614	0.6116 (-1.7559, 2.9792) /0.613	1.2857 (0.4846, 3.4112) /0.614
Max Grade 1	3 (<1%)	4 (1%)	0.7477 (0.1660, 3.3672) /0.705	-0.3058 (-1.8829, 1.2713) /0.704	0.7500 (0.1692, 3.3248) /0.705
Max Grade 2	6 (2%)	3 (<1%)	2.0187 (0.5006, 8.1411) /0.323	0.9174 (-0.8669, 2.7018) /0.314	2.0000 (0.5045, 7.9292) /0.324
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depression					
Any Event	3 (<1%)	6 (2%)	0.4954 (0.1228, 1.9978) /0.323	-0.9174 (-2.7018, 0.8669) /0.314	0.5000 (0.1261, 1.9823) /0.324
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Sleep disorder Any Event	1 (<1%)	5 (2%)	0.1975 (0.0230, 1.7002) /0.140	-1.2232 (-2.6816, 0.2352) /0.100	0.2000 (0.0235, 1.7025) /0.141
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Abnormal dreams					
Any Event	0	5 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	4 (1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depressed mood					
Any Event	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 1	3 (<1%)	1 (<1%)	3.0185 (0.3124, 29.1704) /0.340	0.6116 (-0.5825, 1.8058) /0.315	3.0000 (0.3137, 28.6911) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Libido decreased					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nightmare					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Panic attack					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Adjustment disorder with depressed mood					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Drug abuse					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Irritability					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Major depression Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Adjustment disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Adjustment disorder with mixed anxiety and depressed mood					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Agoraphobia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Emotional distress					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Loss of libido					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Mood swings					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nervousness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Post-traumatic stress disorder					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Restlessness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Stress					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Investigations					
Any Event	18 (6%)	30 (9%)	0.5767 (0.3147, 1.0568) /0.075	-3.6697 (-7.6571, 0.3177) /0.071	0.6000 (0.3414, 1.0545) /0.076
Max Grade 1	14 (4%)	20 (6%)	0.6866 (0.3406, 1.3838) /0.293	-1.8349 (-5.2348, 1.5651) /0.290	0.7000 (0.3598, 1.3619) /0.294
Max Grade 2	2 (<1%)	9 (3%)	0.2174 (0.0466, 1.0142) /0.052	-2.1407 (-4.1050, -0.1764) /0.033	0.2222 (0.0484, 1.0206) /0.053
Max Grade 3	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Body temperature increased					
Any Event	2 (<1%)	6 (2%)	0.3292 (0.0660, 1.6433) /0.176	-1.2232 (-2.9055, 0.4590) /0.154	0.3333 (0.0678, 1.6394) /0.176
Max Grade 1	1 (<1%)	6 (2%)	0.1641 (0.0196, 1.3708) /0.095	-1.5291 (-3.1020, 0.0439) /0.057	0.1667 (0.0202, 1.3767) /0.096
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Weight increased					
Any Event	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Alanine aminotransferase increased					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatine phosphokinase increased					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood pressure increased					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood cholesterol increased					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Blood glucose increased					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lipase increased					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Low density lipoprotein increased					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Weight decreased					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Aspartate aminotransferase increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood bilirubin increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood bilirubin unconjugated increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood creatinine increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood triglycerides increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
CD4 lymphocytes decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Campylobacter test positive Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chlamydia test positive					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Creatinine renal clearance decreased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Culture urine positive					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Escherichia test positive					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haematocrit increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemoglobin increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatic enzyme increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Intraocular pressure increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Muscle enzyme increased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Parasite stool test positive Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Shigella test positive					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Transaminases increased					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
White blood cell count decreased					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Reproductive system and breast disorders					
Any Event	16 (5%)	15 (5%)	1.0701 (0.5200, 2.2022) /0.854	0.3058 (-2.9512, 3.5629) /0.854	1.0667 (0.5363, 2.1214) /0.854
Max Grade 1	10 (3%)	10 (3%)	1.0000 (0.4106, 2.4357) />0.999	<0.0001 (-2.6392, 2.6392) />0.999	1.0000 (0.4219, 2.3703) />0.999
Max Grade 2	6 (2%)	5 (2%)	1.2037 (0.3637, 3.9839) /0.761	0.3058 (-1.6652, 2.2768) /0.761	1.2000 (0.3699, 3.8931) /0.761
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Erectile dysfunction					
Any Event	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 1	2 (<1%)	4 (1%)	0.4969 (0.0904, 2.7320) /0.421	-0.6116 (-2.0723, 0.8490) /0.412	0.5000 (0.0922, 2.7109) /0.422
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Prostatomegaly Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Testicular cyst Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Atrophic vulvovaginitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Balanoposthitis Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Benign prostatic hyperplasia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Breast cyst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Breast pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cervical dysplasia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Genital erythema					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Haematospermia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Menorrhagia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Penile burning sensation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Penile discharge Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Penile pain Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Priapism					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Prostatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Testicular mass Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Testicular pain Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Testicular torsion					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Testis discomfort					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Uterine polyp					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vaginal discharge					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Any Event	9 (3%)	18 (6%)	0.4858 (0.2150, 1.0980) /0.083	-2.7523 (-5.7945, 0.2899) /0.076	0.5000 (0.2280, 1.0966) /0.084
Max Grade 1	8 (2%)	15 (5%)	0.5216 (0.2181, 1.2478) /0.144	-2.1407 (-4.9594, 0.6781) /0.137	0.5333 (0.2293, 1.2407) /0.144
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anogenital warts					
Any Event	3 (<1%)	7 (2%)	0.4233 (0.1085, 1.6513) /0.216	-1.2232 (-3.1018, 0.6553) /0.202	0.4286 (0.1118, 1.6429) /0.217
Max Grade 1	3 (<1%)	6 (2%)	0.4954 (0.1228, 1.9978) /0.323	-0.9174 (-2.7018, 0.8669) /0.314	0.5000 (0.1261, 1.9823) /0.324
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Skin papilloma					
Any Event	0	6 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	6 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Fibrous histiocytoma Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Acrochordon					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Basal cell carcinoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diffuse large B-cell lymphoma Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 5	0	0			
Fibroma Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Glioblastoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 5	0	0			
Kaposi's sarcoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lipoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Lipoma of breast					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethral papilloma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Uterine leiomyoma					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Vascular disorders					
Any Event	13 (4%)	13 (4%)	1.0000 (0.4563, 2.1913) />0.999	<0.0001 (-2.9949, 2.9949) />0.999	1.0000 (0.4708, 2.1240) />0.999
Max Grade 1	11 (3%)	11 (3%)	1.0000 (0.4273, 2.3400) />0.999	<0.0001 (-2.7636, 2.7636) />0.999	1.0000 (0.4397, 2.2740) />0.999
Max Grade 2	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypertension Any Event	9 (3%)	6 (2%)	1.5142 (0.5327, 4.3035) /0.436	0.9174 (-1.3761, 3.2110) /0.433	1.5000 (0.5401, 4.1663) /0.437
Max Grade 1	8 (2%)	5 (2%)	1.6150 (0.5227, 4.9898) /0.405	0.9174 (-1.2209, 3.0558) /0.400	1.6000 (0.5290, 4.8394) /0.405
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Flushing					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Haematoma					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Peripheral venous disease					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blood pressure inadequately controlled					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hot flush					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Hypotension					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Peripheral coldness					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Thrombophlebitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Varicose vein Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Eye disorders					
Any Event	7 (2%)	16 (5%)	0.4252 (0.1726, 1.0477) /0.063	-2.7523 (-5.5679, 0.0633) /0.055	0.4375 (0.1824, 1.0494) /0.064
Max Grade 1	2 (<1%)	11 (3%)	0.1768 (0.0389, 0.8039) /0.025	-2.7523 (-4.8814, -0.6232) /0.011	0.1818 (0.0406, 0.8139) /0.026
Max Grade 2	5 (2%)	4 (1%)	1.2539 (0.3337, 4.7117) /0.738	0.3058 (-1.4798, 2.0914) /0.737	1.2500 (0.3387, 4.6134) /0.738
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blepharitis Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Conjunctivitis allergic					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Retinal detachment					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Blepharospasm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cataract					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chalazion					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Diplopia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Dry eye					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eye pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eyelid cyst					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Eyelid oedema					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Glaucoma					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Iritis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Mydriasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ocular hyperaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pterygium					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ulcerative keratitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vision blurred					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Vitreous floaters					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal and urinary disorders					
Any Event	6 (2%)	16 (5%)	0.3633 (0.1404, 0.9405) /0.037	-3.0581 (-5.8118, -0.3044) /0.030	0.3750 (0.1486, 0.9463) /0.038
Max Grade 1	4 (1%)	12 (4%)	0.3251 (0.1037, 1.0187) /0.054	-2.4465 (-4.8070, -0.0859) /0.042	0.3333 (0.1086, 1.0228) /0.055
Max Grade 2	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Dysuria					
Any Event	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 1	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Renal colic Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Micturition urgency					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nocturia					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pollakiuria					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haematuria					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Leukocyturia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Micturition disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Nephrolithiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nephropathy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ureterolithiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urethral disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Urinary tract disorder					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Ear and labyrinth disorders					
Any Event	8 (2%)	12 (4%)	0.6583 (0.2655, 1.6322) /0.367	-1.2232 (-3.8608, 1.4143) /0.363	0.6667 (0.2761, 1.6095) /0.367
Max Grade 1	8 (2%)	10 (3%)	0.7950 (0.3097, 2.0404) /0.633	-0.6116 (-3.1189, 1.8956) /0.633	0.8000 (0.3198, 2.0014) /0.633
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tinnitus					
Any Event	2 (<1%)	3 (<1%)	0.6646 (0.1103, 4.0038) /0.656	-0.3058 (-1.6407, 1.0291) /0.653	0.6667 (0.1121, 3.9636) /0.656
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vertigo					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cerumen impaction					
Any Event	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	3 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ear discomfort					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Excessive cerumen production					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Deafness neurosensory					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Ear pain					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Eustachian tube dysfunction					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hypoacusis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tympanic membrane perforation					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Immune system disorders					
Any Event	11 (3%)	9 (3%)	1.2300 (0.5028, 3.0089) /0.650	0.6116 (-2.0272, 3.2504) /0.650	1.2222 (0.5133, 2.9101) /0.650
Max Grade 1	7 (2%)	3 (<1%)	2.3625 (0.6056, 9.2167) /0.216	1.2232 (-0.6553, 3.1018) /0.202	2.3333 (0.6087, 8.9449) /0.217
Max Grade 2	4 (1%)	5 (2%)	0.7975 (0.2122, 2.9969) /0.738	-0.3058 (-2.0914, 1.4798) /0.737	0.8000 (0.2168, 2.9526) /0.738
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Seasonal allergy					
Any Event	6 (2%)	5 (2%)	1.2037 (0.3637, 3.9839) /0.761	0.3058 (-1.6652, 2.2768) /0.761	1.2000 (0.3699, 3.8931) /0.761
Max Grade 1	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hypersensitivity					
Any Event	3 (<1%)	3 (<1%)	1.0000 (0.2003, 4.9913) />0.999	<0.0001 (-1.4614, 1.4614) />0.999	1.0000 (0.2033, 4.9182) />0.999
Max Grade 1	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Food allergy					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Drug hypersensitivity					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Metabolism and nutrition disorders					
Any Event	6 (2%)	13 (4%)	0.4515 (0.1695, 1.2027) /0.112	-2.1407 (-4.7098, 0.4285) /0.102	0.4615 (0.1776, 1.1995) /0.113
Max Grade 1	5 (2%)	8 (2%)	0.6192 (0.2004, 1.9130) /0.405	-0.9174 (-3.0558, 1.2209) /0.400	0.6250 (0.2066, 1.8904) /0.405
Max Grade 2	1 (<1%)	4 (1%)	0.2477 (0.0275, 2.2281) /0.213	-0.9174 (-2.2507, 0.4158) /0.177	0.2500 (0.0281, 2.2247) /0.214
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypercholesterolemia					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Vitamin D deficiency					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Decreased appetite					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Obesity					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Type 2 diabetes mellitus					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Cachexia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Gluten sensitivity					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Gout					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Hyperglycaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Hyperlipasaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC
Hypokalaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cardiac disorders					
Any Event	4 (1%)	7 (2%)	0.5661 (0.1641, 1.9527) /0.368	-0.9174 (-2.8873, 1.0524) /0.361	0.5714 (0.1689, 1.9334) /0.368
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	4 (1%)	4 (1%)	1.0000 (0.2480, 4.0328) />0.999	<0.0001 (-1.6849, 1.6849) />0.999	1.0000 (0.2522, 3.9646) />0.999
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Palpitations					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Tachycardia					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Acute myocardial infarction					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Angina pectoris					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Atrial fibrillation					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Cardiac aneurysm					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Ventricular extrasystoles					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Blood and lymphatic system disorders					
Any Event	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Max Grade 1	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 2	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Iron deficiency anaemia					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Anaemia					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Lymph node pain					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Lymphadenopathy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Microcytic anaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neutropenia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Congenital, familial and genetic disorders					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Atrial septal defect					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Benign familial pemphigus					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hydrocele					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Type V hyperlipidaemia					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Endocrine disorders					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hypogonadism					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Goitre					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Hepatobiliary disorders					
Any Event	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Max Grade 1	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
<hr/>					
Cholelithiasis					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Hepatomegaly					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Jaundice					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Social circumstances					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 1	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Menopause					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			
Stress at work					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	0	NC	NC	NC
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pregnancy, puerperium and perinatal conditions					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.01
 Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Abortion spontaneous Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1	0	0	NC	NC	NC
Max Grade 2	0	0	NC	NC	NC
Max Grade 3	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 4	0	0	NC	NC	NC
Max Grade 5	0	0			

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	22 (7%)	35 (11%)	0.6018 (0.3448, 1.0502) /0.074	-3.9755 (-8.2883, 0.3372) /0.071	0.6286 (0.3772, 1.0475) /0.075
General disorders and administration site conditions					
Any Event	7 (2%)	18 (6%)	0.3755 (0.1547, 0.9116) /0.030	-3.3639 (-6.2916, -0.4362) /0.024	0.3889 (0.1646, 0.9185) /0.031
Injection site pain	6 (2%)	17 (5%)	0.3408 (0.1327, 0.8758) /0.025	-3.3639 (-6.1756, -0.5522) /0.019	0.3529 (0.1409, 0.8839) /0.026
Injection site discomfort	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Chest pain	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Fatigue	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injection site discolouration	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site swelling	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site warmth	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pyrexia	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Infections and infestations					
Any Event	5 (2%)	5 (2%)	1.0000 (0.2867, 3.4875) />0.999	<0.0001 (-1.8809, 1.8809) />0.999	1.0000 (0.2923, 3.4215) />0.999
Acute hepatitis B	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Anal abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Diverticulitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Epididymitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Epiglottitis obstructive	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Erysipelas	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Hepatitis E	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Pneumonia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Musculoskeletal and connective tissue disorders					
Any Event	4 (1%)	3 (<1%)	1.3375 (0.2970, 6.0233) /0.705	0.3058 (-1.2713, 1.8829) /0.704	1.3333 (0.3008, 5.9107) /0.705
Intervertebral disc protrusion	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Arthralgia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Costochondritis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Muscle spasms	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Myalgia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Osteoarthritis	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Osteonecrosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Pain in extremity	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rotator cuff syndrome	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Gastrointestinal disorders					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Abdominal pain	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Haemorrhoidal haemorrhage	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Oroantral fistula	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Investigations					
Any Event	2 (<1%)	1 (<1%)	2.0062 (0.1810, 22.2332) /0.571	0.3058 (-0.7297, 1.3413) /0.563	2.0000 (0.1822, 21.9486) /0.571
Body temperature increased	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Transaminases increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
White blood cell count decreased	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Injury, poisoning and procedural complications					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Contusion	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Overdose	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Diffuse large B-cell lymphoma	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Glioblastoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Psychiatric disorders Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Depression	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Major depression	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Blood and lymphatic system disorders Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Microcytic anaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Cardiac disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Acute myocardial infarction	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Ear and labyrinth disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Tympanic membrane perforation	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Eye disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Retinal detachment	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Immune system disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hypersensitivity	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Metabolism and nutrition disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hypercholesterolaemia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nervous system disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Cerebrovascular accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Pregnancy, puerperium and perinatal conditions					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Abortion spontaneous	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.02

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Renal and urinary disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Renal colic	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Respiratory, thoracic and mediastinal disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Sleep apnoea syndrome	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Overall					
Any Event	17 (5%)	11 (3%)	1.5754 (0.7262, 3.4175) /0.250	1.8349 (-1.2649, 4.9346) /0.246	1.5455 (0.7353, 3.2481) /0.251
Infections and infestations					
Any Event	8 (2%)	6 (2%)	1.3417 (0.4603, 3.9107) /0.590	0.6116 (-1.6064, 2.8297) /0.589	1.3333 (0.4678, 3.8001) /0.590
Pneumonia	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571
Acute hepatitis B	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Anal abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Diverticulitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Epiglottitis obstructive	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Erysipelas	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Gastroenteritis Escherichia coli	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.03
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Peritonsillar abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Sialoadenitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Sinusitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastrointestinal disorders Any Event	4 (1%)	1 (<1%)	4.0372 (0.4488, 36.3154) /0.213	0.9174 (-0.4158, 2.2507) /0.177	4.0000 (0.4495, 35.5960) /0.214

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Haemorrhoids	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Anal fistula	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Colitis	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Oroantral fistula	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injury, poisoning and procedural complications Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Head injury	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Overdose	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Musculoskeletal and connective tissue disorders					
Any Event	2 (<1%)	0	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC
Intervertebral disc protrusion	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Rotator cuff syndrome	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Diffuse large B-cell lymphoma	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Glioblastoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nervous system disorders					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Cerebral infarction	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Cerebrovascular accident	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Blood and lymphatic system disorders					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Microcytic anaemia	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Cardiac disorders Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Acute myocardial infarction	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Immune system disorders Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hypersensitivity	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Pregnancy, puerperium and perinatal conditions					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Abortion spontaneous	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Reproductive system and breast disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Priapism	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.03

Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 - by System Organ Class and Preferred Term (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Respiratory, thoracic and mediastinal disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Sleep apnoea syndrome	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Overall					
Any Event	9 (3%)	11 (3%)	0.8130 (0.3323, 1.9890) /0.650	-0.6116 (-3.2504, 2.0272) /0.650	0.8182 (0.3436, 1.9481) /0.650
General disorders and administration site conditions					
Any Event	5 (2%)	4 (1%)	1.2539 (0.3337, 4.7117) /0.738	0.3058 (-1.4798, 2.0914) /0.737	1.2500 (0.3387, 4.6134) /0.738
Injection site pain	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Fatigue	1 (<1%)	2 (<1%)	0.4985 (0.0450, 5.5243) /0.571	-0.3058 (-1.3413, 0.7297) /0.563	0.5000 (0.0456, 5.4872) /0.571

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Pyrexia	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Asthenia	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Chills	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injection site discolouration	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site hypersensitivity	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.04
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Injection site necrosis	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site nodule	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injection site swelling	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Injection site warmth	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Infections and infestations					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Acute hepatitis B	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Influenza	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Injection site abscess	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.
 NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Nervous system disorders					
Any Event	1 (<1%)	3 (<1%)	0.3313 (0.0343, 3.2015) /0.340	-0.6116 (-1.8058, 0.5825) /0.315	0.3333 (0.0349, 3.1879) /0.340
Headache	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Disturbance in attention	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Dizziness	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Presyncope	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Skin and subcutaneous tissue disorders					
Any Event	2 (<1%)	2 (<1%)	1.0000 (0.1400, 7.1419) />0.999	<0.0001 (-1.1951, 1.1951) />0.999	1.0000 (0.1417, 7.0566) />0.999
Hyperhidrosis	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Rash maculo-papular	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Skin lesion	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Psychiatric disorders					
Any Event	0	3 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Abnormal dreams	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Depression	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Insomnia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Sleep disorder	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Neoplasms benign, malignant and unspecified (incl cysts and polyps) Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Diffuse large B-cell lymphoma	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Glioblastoma	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Gastrointestinal disorders Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value
Nausea	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Immune system disorders Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Hypersensitivity	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Investigations Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Transaminases increased	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.04

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation
 (Maintenance Phase) - by System Organ Class and Preferred Term - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Musculoskeletal and connective tissue disorders					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Myalgia	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Population: Safety

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Table 3.06
Analysis of AESI - Proportion of Subjects with Any Adverse Event of Hepatotoxicity
by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

No data to report

Table 3.07

Analysis of AESI - Proportion of Subjects with Any Hypersensitivity Reaction (HSR) Leading to Study Discontinuation by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Hypersensitivity Reaction (HSR)					
Any Event	1 (<1%)	1 (<1%)	1.0000 (0.0623, 16.0556) />0.999	<0.0001 (-0.8464, 0.8464) />0.999	1.0000 (0.0628, 15.9198) />0.999
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3 or 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively) with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Protocol: 207966
Population: Safety

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Table 3.09
Analysis of AESI - Proportion of Subjects with Any Event of QT Prolongation
by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

No data to report

Table 3.11
 Analysis of AESI - Proportion of Subjects with Any Seizures or Seizure-like Adverse Event
 by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Seizures or Seizure-like Adverse Event					
Any Event	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1 or 2	0	2 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either
 treatment group may lead to unreliable statistical estimates.

Table 3.12
 Analysis of AESI - Proportion of Subjects with Any Event of Weight Gain by Severity
 (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Weight Gain					
Any Event	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 1 or 2	5 (2%)	3 (<1%)	1.6770 (0.3975, 7.0756) /0.482	0.6116 (-1.0726, 2.2959) /0.477	1.6667 (0.4016, 6.9168) /0.482
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment
 group may lead to unreliable statistical estimates.

Table 3.13
Analysis of AESI - Proportion of Subjects with Any Event of Rhabdomyolysis by Severity
(Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

No data to report

Table 3.14
 Analysis of AESI - Proportion of Subjects with Any Event of Pancreatitis
 by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Pancreatitis					
Any Event	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 1 or 2	1 (<1%)	0	>999 (>999, >999) /NC	0.3058 (-10.7225, 11.3341) /0.957	>999 (>999, >999) /NC
Max Grade 3 or 4	0	0	NC	NC	NC
Any Serious AE	0	0	NC	NC	NC

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment
 group may lead to unreliable statistical estimates.

Table 3.15

Analysis of AESI - Proportion of Subjects with Any Event Indicating an Impact on Creatinine
by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

No data to report

Table 3.16
 Analysis of AESI - Proportion of Subjects with Any Event of Relevance to Safety in Pregnancy
 by Severity (Maintenance Phase) - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value

Subjects with Any Event of Relevance to Safety in Pregnancy					
Any Event	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Max Grade 1 or 2	0	0	NC	NC	NC
Max Grade 3 or 4	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999
Any Serious AE	0	1 (<1%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999

Note: "Any Event" represents subjects with any AE reported, regardless of SOCs selected.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk.
 RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively)
 with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either
 treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event		Q8W	Q4W	OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	(N=327)	(N=327)	/p-value	/p-value	/p-value	p-value(RR)
Overall		273 (83%)	268 (82%)	1.1130 (0.7418, 1.6700) /0.605	1.5291 (-4.2647, 7.3228) /0.605	1.0187 (0.9497, 1.0926) /0.605	
Age (years)	<35	77/ 84 (92%)	81/ 98 (83%)	2.3086 (0.9074, 5.8738) /0.079	9.0136 (-0.5329, 18.5601) /0.064	1.1091 (0.9923, 1.2396) /0.068	0.161
	35 - <50	128/154 (83%)	116/143 (81%)	1.1459 (0.6325, 2.0760) /0.653	1.9980 (-6.7283, 10.7243) /0.654	1.0246 (0.9212, 1.1397) /0.654	
	>=50	68/ 89 (76%)	71/ 86 (83%)	0.6841 (0.3260, 1.4358) /0.316	-6.1536 (-18.0756, 5.7684) /0.312	0.9255 (0.7958, 1.0762) /0.314	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event		Q8W	Q4W	OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	(N=327)	(N=327)	/p-value	/p-value	/p-value	p-value(RR)
Sex at Birth	Female	52/ 73 (71%)	54/ 75 (72%)	0.9630 (0.4712, 1.9680) /0.918	-0.7671 (-15.2961, 13.7618) /0.918	0.9893 (0.8077, 1.2119) /0.918	0.749
	Male	221/254 (87%)	214/252 (85%)	1.1892 (0.7192, 1.9662) /0.499	2.0872 (-3.9639, 8.1384) /0.499	1.0246 (0.9549, 1.0994) /0.499	
Race	White	200/238 (84%)	215/256 (84%)	1.0037 (0.6201, 1.6245) /0.988	0.0492 (-6.4191, 6.5176) /0.988	1.0006 (0.9264, 1.0807) /0.988	0.311
	Non-White	73/ 89 (82%)	53/ 71 (75%)	1.5495 (0.7242, 3.3155) /0.259	7.3746 (-5.5110, 20.2602) /0.262	1.0988 (0.9299, 1.2983) /0.268	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	97/118 (82%)	105/135 (78%)	1.3197 (0.7084, 2.4587) /0.382	4.4256 (-5.4135, 14.2647) /0.378	1.0569 (0.9344, 1.1955) /0.379	0.631
	Europe	144/165 (87%)	134/155 (86%)	1.0746 (0.5616, 2.0564) /0.828	0.8211 (-6.5876, 8.2298) /0.828	1.0095 (0.9269, 1.0994) /0.828	
	Rest of World	32/ 44 (73%)	29/ 37 (78%)	0.7356 (0.2637, 2.0525) /0.558	-5.6511 (-24.3357, 13.0335) /0.553	0.9279 (0.7243, 1.1888) /0.554	

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2		Q8W	Q4W	OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	(N=327)	(N=327)	/p-value	/p-value	/p-value	p-value(RR)
Overall		265 (81%)	251 (77%)	1.2942 (0.8875, 1.8872) /0.180	4.2813 (-1.9643, 10.5270) /0.179	1.0558 (0.9752, 1.1430) /0.180	
Age (years)	<35	76/ 84 (90%)	78/ 98 (80%)	2.4359 (1.0117, 5.8648) /0.047	10.8844 (0.7317, 21.0370) /0.036	1.1368 (1.0063, 1.2841) /0.039	0.374
	35 - <50	123/154 (80%)	108/143 (76%)	1.2858 (0.7432, 2.2246) /0.369	4.3457 (-5.1286, 13.8199) /0.369	1.0575 (0.9357, 1.1953) /0.371	
	>=50	66/ 89 (74%)	65/ 86 (76%)	0.9271 (0.4680, 1.8365) /0.828	-1.4241 (-14.2754, 11.4272) /0.828	0.9812 (0.8264, 1.1649) /0.828	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	51/ 73 (70%)	52/ 75 (69%)	1.0253 (0.5089, 2.0660) /0.944	0.5297 (-14.2926, 15.3519) /0.944	1.0076 (0.8144, 1.2468) /0.944	0.624
	Male	214/254 (84%)	199/252 (79%)	1.4249 (0.9053, 2.2428) /0.126	5.2837 (-1.4531, 12.0205) /0.124	1.0669 (0.9819, 1.1592) /0.126	
Race	White	194/238 (82%)	199/256 (78%)	1.2629 (0.8132, 1.9614) /0.299	3.7782 (-3.3137, 10.8701) /0.296	1.0486 (0.9591, 1.1465) /0.297	0.703
	Non-White	71/ 89 (80%)	52/ 71 (73%)	1.4412 (0.6895, 3.0125) /0.331	6.5358 (-6.7187, 19.7903) /0.334	1.0892 (0.9141, 1.2979) /0.339	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	92/118 (78%)	96/135 (71%)	1.4375 (0.8107, 2.5488) /0.214	6.8550 (-3.8400, 17.5499) /0.209	1.0964 (0.9493, 1.2663) /0.211	0.528
	Europe	141/165 (85%)	126/155 (81%)	1.3522 (0.7482, 2.4438) /0.318	4.1642 (-3.9986, 12.3271) /0.317	1.0512 (0.9528, 1.1598) /0.319	
	Rest of World	32/ 44 (73%)	29/ 37 (78%)	0.7356 (0.2637, 2.0525) /0.558	-5.6511 (-24.3357, 13.0335) /0.553	0.9279 (0.7243, 1.1888) /0.554	

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		8 (2%)	17 (5%)	0.4573 (0.1945, 1.0750) /0.073	-2.7523 (-5.6838, 0.1792) /0.066	0.4706 (0.2060, 1.0751) /0.074	
Age (years)	<35	1/ 84 (1%)	3/ 98 (3%)	0.3815 (0.0389, 3.7385) /0.408	-1.8707 (-5.9953, 2.2538) /0.374	0.3889 (0.0412, 3.6688) /0.409	0.818
	35 - <50	5/154 (3%)	8/143 (6%)	0.5663 (0.1809, 1.7730) /0.329	-2.3477 (-7.0406, 2.3453) /0.327	0.5804 (0.1944, 1.7329) /0.330	
	>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.936
	Male	7/254 (3%)	15/252 (6%)	0.4478 (0.1794, 1.1176) /0.085	-3.1965 (-6.7443, 0.3513) /0.077	0.4630 (0.1920, 1.1163) /0.086	
Race	White	6/238 (3%)	16/256 (6%)	0.3879 (0.1492, 1.0086) /0.052	-3.7290 (-7.3009, -0.1570) /0.041	0.4034 (0.1605, 1.0137) /0.053	0.274
	Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.
 Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	5/118 (4%)	9/135 (7%)	0.6195 (0.2017, 1.9030) /0.403	-2.4294 (-7.9895, 3.1308) /0.392	0.6356 (0.2191, 1.8437) /0.404	0.787
	Europe	3/165 (2%)	8/155 (5%)	0.3403 (0.0886, 1.3068) /0.116	-3.3431 (-7.3789, 0.6927) /0.104	0.3523 (0.0952, 1.3038) /0.118	
	Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		1 (<1%)	0				
Age (years)	<35	1/ 84 (1%)	0/ 98				
	35 - <50	0/154	0/143				
	>=50	0/ 89	0/ 86				
Sex at Birth	Female	1/ 73 (1%)	0/ 75				
	Male	0/254	0/252				
Race	White	1/238 (<1%)	0/256				
	Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.05
 Analysis of AESI - Proportion of Subjects with Any ISR by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/118	0/135				
	Europe	1/165 (<1%)	0/155				
	Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		8 (2%)	16 (5%)	0.4875 (0.2057, 1.1553) /0.103	-2.4465 (-5.3223, 0.4294) /0.095	0.5000 (0.2170, 1.1521) /0.104	
Age (years)	<35	3/ 84 (4%)	6/ 98 (6%)				
	35 - <50	4/154 (3%)	5/143 (3%)				
	>=50	1/ 89 (1%)	5/ 86 (6%)				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	2/ 73 (3%)	3/ 75 (4%)	0.6761 (0.1097, 4.1683) /0.673	-1.2603 (-7.0646, 4.5441) /0.670	0.6849 (0.1178, 3.9809) /0.673	0.696
	Male	6/254 (2%)	13/252 (5%)	0.4448 (0.1663, 1.1893) /0.106	-2.7965 (-6.1051, 0.5120) /0.098	0.4579 (0.1768, 1.1858) /0.108	
Race	White	4/238 (2%)	12/256 (5%)	0.3476 (0.1105, 1.0930) /0.071	-3.0068 (-6.0681, 0.0544) /0.054	0.3585 (0.1173, 1.0964) /0.072	0.368
	Non-White	4/ 89 (4%)	4/ 71 (6%)	0.7882 (0.1901, 3.2689) /0.743	-1.1394 (-8.0163, 5.7375) /0.745	0.7978 (0.2067, 3.0784) /0.743	

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	3/118 (3%)	6/135 (4%)				
	Europe	2/165 (1%)	6/155 (4%)				
	Rest of World	3/ 44 (7%)	4/ 37 (11%)				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		8 (2%)	16 (5%)	0.4875 (0.2057, 1.1553) /0.103	-2.4465 (-5.3223, 0.4294) /0.095	0.5000 (0.2170, 1.1521) /0.104	
Age (years)	<35	3/ 84 (4%)	6/ 98 (6%)				
	35 - <50	4/154 (3%)	5/143 (3%)				
	>=50	1/ 89 (1%)	5/ 86 (6%)				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08
 Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) -
 Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	2/ 73 (3%)	3/ 75 (4%)	0.6761 (0.1097, 4.1683) /0.673	-1.2603 (-7.0646, 4.5441) /0.670	0.6849 (0.1178, 3.9809) /0.673	0.696
	Male	6/254 (2%)	13/252 (5%)	0.4448 (0.1663, 1.1893) /0.106	-2.7965 (-6.1051, 0.5120) /0.098	0.4579 (0.1768, 1.1858) /0.108	
Race	White	4/238 (2%)	12/256 (5%)	0.3476 (0.1105, 1.0930) /0.071	-3.0068 (-6.0681, 0.0544) /0.054	0.3585 (0.1173, 1.0964) /0.072	0.368
	Non-White	4/ 89 (4%)	4/ 71 (6%)	0.7882 (0.1901, 3.2689) /0.743	-1.1394 (-8.0163, 5.7375) /0.745	0.7978 (0.2067, 3.0784) /0.743	

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	3/118 (3%)	6/135 (4%)				
	Europe	2/165 (1%)	6/155 (4%)				
	Rest of World	3/ 44 (7%)	4/ 37 (11%)				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4		Q8W	Q4W	OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	(N=327)	(N=327)	/p-value	/p-value	/p-value	p-value(RR)
Overall		0	0				
Age (years)	<35	0/ 84	0/ 98				
	35 - <50	0/154	0/143				
	>=50	0/ 89	0/ 86				
Sex at Birth	Female	0/ 73	0/ 75				
	Male	0/254	0/252				
Race	White	0/238	0/256				
	Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/118	0/135				
	Europe	0/165	0/155				
	Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	0				
Age (years)	<35	0/ 84	0/ 98				
	35 - <50	0/154	0/143				
	>=50	0/ 89	0/ 86				
Sex at Birth	Female	0/ 73	0/ 75				
	Male	0/254	0/252				
Race	White	0/238	0/256				
	Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Table 3.08

Analysis of AESI - Proportion of Subjects with Any Event of Rash by Severity (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events

Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/118	0/135				
	Europe	0/165	0/155				
	Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any respective AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		32 (10%)	45 (14%)	0.6798 (0.4199, 1.1005) /0.116	-3.9755 (-8.9063, 0.9553) /0.114	0.7111 (0.4642, 1.0894) /0.117	
Age (years)	<35	13/ 84 (15%)	16/ 98 (16%)	0.9384 (0.4226, 2.0839) /0.876	-0.8503 (-11.4979, 9.7972) /0.876	0.9479 (0.4844, 1.8549) /0.876	0.618
	35 - <50	13/154 (8%)	19/143 (13%)	0.6017 (0.2855, 1.2682) /0.182	-4.8452 (-11.9324, 2.2421) /0.180	0.6353 (0.3258, 1.2388) /0.183	
	>=50	6/ 89 (7%)	10/ 86 (12%)	0.5494 (0.1906, 1.5840) /0.268	-4.8863 (-13.4325, 3.6598) /0.262	0.5798 (0.2203, 1.5260) /0.270	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	1/ 73 (1%)	7/ 75 (9%)	0.1349 (0.0162, 1.1256) /0.064	-7.9635 (-15.0665, -0.8605) /0.028	0.1468 (0.0185, 1.1636) /0.069	0.058
	Male	31/254 (12%)	38/252 (15%)	0.7829 (0.4701, 1.3038) /0.347	-2.8746 (-8.8518, 3.1025) /0.346	0.8094 (0.5206, 1.2582) /0.347	
Race	White	26/238 (11%)	32/256 (13%)	0.8585 (0.4951, 1.4887) /0.587	-1.5756 (-7.2430, 4.0917) /0.586	0.8739 (0.5373, 1.4215) /0.587	0.092
	Non-White	6/ 89 (7%)	13/ 71 (18%)	0.3225 (0.1159, 0.8979) /0.030	-11.5683 (-21.9636, -1.1729) /0.029	0.3682 (0.1474, 0.9199) /0.032	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Any Event							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	12/118 (10%)	25/135 (19%)	0.4981 (0.2381, 1.0421) /0.064	-8.3490 (-16.8741, 0.1760) /0.055	0.5492 (0.2888, 1.0440) /0.067	0.480
	Europe	16/165 (10%)	17/155 (11%)	0.8717 (0.4239, 1.7924) /0.709	-1.2708 (-7.9482, 5.4066) /0.709	0.8841 (0.4632, 1.6877) /0.709	
	Rest of World	4/ 44 (9%)	3/ 37 (8%)	1.1333 (0.2369, 5.4215) /0.875	0.9828 (-11.2446, 13.2102) /0.875	1.1212 (0.2679, 4.6931) /0.876	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		32 (10%)	42 (13%)	0.7361 (0.4519, 1.1989) /0.218	-3.0581 (-7.9080, 1.7918) /0.217	0.7619 (0.4938, 1.1755) /0.219	
Age (years)	<35	13/ 84 (15%)	15/ 98 (15%)	1.0131 (0.4519, 2.2717) /0.975	0.1701 (-10.3483, 10.6884) /0.975	1.0111 (0.5106, 2.0021) /0.975	0.642
	35 - <50	13/154 (8%)	18/143 (13%)	0.6403 (0.3016, 1.3594) /0.246	-4.1459 (-11.1342, 2.8425) /0.245	0.6706 (0.3411, 1.3186) /0.247	
	>=50	6/ 89 (7%)	9/ 86 (10%)	0.6185 (0.2103, 1.8185) /0.383	-3.7235 (-12.0296, 4.5825) /0.380	0.6442 (0.2395, 1.7329) /0.384	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Sex at Birth	Female	1/ 73 (1%)	6/ 75 (8%)	0.1597 (0.0187, 1.3611) /0.093	-6.6301 (-13.3240, 0.0637) /0.052	0.1712 (0.0211, 1.3876) /0.098	0.084
	Male	31/254 (12%)	36/252 (14%)	0.8341 (0.4982, 1.3965) /0.490	-2.0810 (-7.9862, 3.8242) /0.490	0.8543 (0.5461, 1.3365) /0.490	
Race	White	26/238 (11%)	29/256 (11%)	0.9600 (0.5475, 1.6831) /0.887	-0.4038 (-5.9517, 5.1442) /0.887	0.9644 (0.5855, 1.5885) /0.887	0.062
	Non-White	6/ 89 (7%)	13/ 71 (18%)	0.3225 (0.1159, 0.8979) /0.030	-11.5683 (-21.9636, -1.1729) /0.029	0.3682 (0.1474, 0.9199) /0.032	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 1 or 2							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	12/118 (10%)	23/135 (17%)	0.5513 (0.2612, 1.1633) /0.118	-6.8675 (-15.2317, 1.4966) /0.108	0.5969 (0.3107, 1.1466) /0.121	0.543
	Europe	16/165 (10%)	16/155 (10%)	0.9329 (0.4494, 1.9367) /0.852	-0.6256 (-7.2081, 5.9569) /0.852	0.9394 (0.4868, 1.8127) /0.852	
	Rest of World	4/ 44 (9%)	3/ 37 (8%)	1.1333 (0.2369, 5.4215) /0.875	0.9828 (-11.2446, 13.2102) /0.875	1.1212 (0.2679, 4.6931) /0.876	

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

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Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4		Q8W	Q4W	OR (95%CI)	RD (95%CI)	RR (95%CI)	Interaction
Subgroup	Category	(N=327)	(N=327)	/p-value	/p-value	/p-value	p-value(RR)
Overall		0	3 (<1%)				
Age (years)	<35	0/ 84	1/ 98 (1%)				
	35 - <50	0/154	1/143 (<1%)				
	>=50	0/ 89	1/ 86 (1%)				
Sex at Birth	Female	0/ 73	1/ 75 (1%)				
	Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Maximum Toxicity Grade 3 or 4							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Race	White	0/238	3/256 (1%)				
	Non-White	0/ 89	0/ 71				
Region	North America	0/118	2/135 (1%)				
	Europe	0/165	1/155 (<1%)				
	Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Overall		0	1 (<1%)				
Age (years)	<35	0/ 84	0/ 98				
	35 - <50	0/154	1/143 (<1%)				
	>=50	0/ 89	0/ 86				
Sex at Birth	Female	0/ 73	0/ 75				
	Male	0/254	1/252 (<1%)				
Race	White	0/238	1/256 (<1%)				
	Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.10
 Analysis of AESI - Proportion of Subjects with Any Neuropsychiatric Adverse Event by Severity
 (Maintenance Phase) - Overall and by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

AE type: Serious Adverse Events							
Subgroup	Category	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Interaction p-value(RR)
Region	North America	0/118	0/135				
	Europe	0/165	1/155 (<1%)				
	Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any respective AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of a subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. RD, OR and RR are obtained from genmod models (link = identity, logit or log, respectively), for overall and subgroup (using a 'by subgroup statement'). P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Neuropsychiatric AE: "depression", "anxiety", "suicidal ideation" and "sleep disorders".

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
<35	81/ 84 (96%)	94/ 98 (96%)				
35 - <50	141/154 (92%)	134/143 (94%)				
>=50	81/ 89 (91%)	82/ 86 (95%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	78/ 84 (93%)	83/ 98 (85%)				
35 - <50	131/154 (85%)	120/143 (84%)				
>=50	70/ 89 (79%)	72/ 86 (84%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
<35	75/ 84 (89%)	78/ 98 (80%)				
35 - <50	120/154 (78%)	113/143 (79%)				
>=50	67/ 89 (75%)	65/ 86 (76%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
<35	12/ 84 (14%)	15/ 98 (15%)	0.9222 (0.4053, 2.0983) /0.847	-1.0204 (-11.3554, 9.3146) /0.847	0.9333 (0.4631, 1.8812) /0.847	0.100
35 - <50	12/154 (8%)	29/143 (20%)	0.3322 (0.1623, 0.6801) /0.003	-12.4875 (-20.3203, -4.6547) /0.002	0.3842 (0.2040, 0.7237) /0.003	
>=50	6/ 89 (7%)	18/ 86 (21%)	0.2731 (0.1027, 0.7262) /0.009	-14.1887 (-24.2415, -4.1358) /0.006	0.3221 (0.1343, 0.7728) /0.011	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
<35	4/ 84 (5%)	4/ 98 (4%)				
35 - <50	15/154 (10%)	12/143 (8%)				
>=50	7/ 89 (8%)	13/ 86 (15%)				
Pyrexia						
<35	8/ 84 (10%)	10/ 98 (10%)				
35 - <50	8/154 (5%)	16/143 (11%)				
>=50	5/ 89 (6%)	8/ 86 (9%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<35	6/ 84 (7%)	6/ 98 (6%)				
35 - <50	14/154 (9%)	11/143 (8%)				
>=50	3/ 89 (3%)	11/ 86 (13%)				
Injection site swelling						
<35	8/ 84 (10%)	3/ 98 (3%)				
35 - <50	9/154 (6%)	11/143 (8%)				
>=50	6/ 89 (7%)	5/ 86 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	3/ 84 (4%)	10/ 98 (10%)	0.3259 (0.0866, 1.2262) /0.097	-6.6327 (-13.8206, 0.5553) /0.071	0.3500 (0.0996, 1.2300) /0.102	0.939
35 - <50	4/154 (3%)	10/143 (7%)	0.3547 (0.1087, 1.1574) /0.086	-4.3956 (-9.2724, 0.4811) /0.077	0.3714 (0.1192, 1.1579) /0.088	
>=50	1/ 89 (1%)	4/ 86 (5%)	0.2330 (0.0255, 2.1275) /0.197	-3.5276 (-8.4879, 1.4328) /0.163	0.2416 (0.0275, 2.1182) /0.200	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	9/143 (6%)				
>=50	1/ 89 (1%)	5/ 86 (6%)				
Asthenia						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	6/154 (4%)	4/143 (3%)				
>=50	5/ 89 (6%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	6/154 (4%)	9/143 (6%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Chills						
<35	1/ 84 (1%)	0/ 98				
35 - <50	6/154 (4%)	6/143 (4%)				
>=50	5/ 89 (6%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	5/143 (3%)				
>=50	0/ 89	6/ 86 (7%)				
Injection site bruising						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	5/154 (3%)	4/143 (3%)				
>=50	2/ 89 (2%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Injection site warmth						
<35	2/ 84 (2%)	0/ 98				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				
Injection site haematoma						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	2/ 89 (2%)	0/ 86				
Discomfort						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Feeling hot						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Nodule						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Vessel puncture site haematoma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Gait disturbance						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site papule						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Chronic fatigue syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Induration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Inflammation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discharge						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site fibrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site mass						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Injection site rash						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mass						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Oedema peripheral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Sluggishness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Thirst						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xerosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	53/ 84 (63%)	65/ 98 (66%)	0.8680 (0.4717, 1.5972) /0.649	-3.2313 (-17.1609, 10.6983) /0.649	0.9513 (0.7665, 1.1806) /0.650	0.704
35 - <50	83/154 (54%)	89/143 (62%)	0.7093 (0.4463, 1.1273) /0.146	-8.3417 (-19.5273, 2.8440) /0.144	0.8660 (0.7133, 1.0514) /0.146	
>=50	40/ 89 (45%)	47/ 86 (55%)	0.6774 (0.3734, 1.2288) /0.200	-9.7073 (-24.4555, 5.0408) /0.197	0.8224 (0.6093, 1.1100) /0.201	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<35	12/ 84 (14%)	15/ 98 (15%)				
35 - <50	22/154 (14%)	23/143 (16%)				
>=50	14/ 89 (16%)	11/ 86 (13%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
<35	8/ 84 (10%)	16/ 98 (16%)	0.5395 (0.2184, 1.3325) /0.181	-6.8027 (-16.4440, 2.8386) /0.167	0.5833 (0.2629, 1.2945) /0.185	0.807
35 - <50	18/154 (12%)	22/143 (15%)	0.7279 (0.3727, 1.4216) /0.352	-3.6963 (-11.4885, 4.0959) /0.353	0.7597 (0.4254, 1.3567) /0.353	
>=50	9/ 89 (10%)	15/ 86 (17%)	0.5325 (0.2195, 1.2916) /0.163	-7.3295 (-17.5057, 2.8467) /0.158	0.5798 (0.2681, 1.2540) /0.166	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	4/ 84 (5%)	9/ 98 (9%)	0.4944 (0.1466, 1.6679) /0.256	-4.4218 (-11.7315, 2.8880) /0.236	0.5185 (0.1656, 1.6232) /0.259	0.989
35 - <50	6/154 (4%)	12/143 (8%)	0.4426 (0.1615, 1.2124) /0.113	-4.4955 (-9.9719, 0.9809) /0.108	0.4643 (0.1790, 1.2043) /0.115	
>=50	1/ 89 (1%)	2/ 86 (2%)	0.4773 (0.0425, 5.3620) /0.549	-1.2020 (-5.0674, 2.6634) /0.542	0.4831 (0.0446, 5.2313) /0.549	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pharyngitis						
<35	5/ 84 (6%)	8/ 98 (8%)				
35 - <50	5/154 (3%)	5/143 (3%)				
>=50	1/ 89 (1%)	5/ 86 (6%)				
Syphilis						
<35	3/ 84 (4%)	10/ 98 (10%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bronchitis						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	5/154 (3%)	4/143 (3%)				
>=50	5/ 89 (6%)	4/ 86 (5%)				
Influenza						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	5/154 (3%)	5/143 (3%)				
>=50	2/ 89 (2%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gonorrhoea						
<35	9/ 84 (11%)	4/ 98 (4%)				
35 - <50	0/154	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				
Sinusitis						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	7/143 (5%)				
>=50	1/ 89 (1%)	0/ 86				
Chlamydial infection						
<35	5/ 84 (6%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Viral infection						
<35	5/ 84 (6%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
<35	2/ 84 (2%)	7/ 98 (7%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Respiratory tract infection						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
<35	0/ 84	7/ 98 (7%)				
35 - <50	4/154 (3%)	0/143				
>=50	0/ 89	0/ 86				
Conjunctivitis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
<35	3/ 84 (4%)	4/ 98 (4%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oral herpes						
<35	0/ 84	3/ 98 (3%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Urethritis						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Folliculitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Herpes zoster						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Ear infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Furuncle						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Hordeolum						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	3/ 86 (3%)				
Urethritis gonococcal						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Gingivitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Mycoplasma genitalium infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				
Tooth infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Body tinea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cellulitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oral candidiasis						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Paronychia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotons illitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Secondary syphilis						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Urethritis chlamydial						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaginal infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Viral pharyngitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Cystitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enteritis infectious						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Epididymitis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia urinary tract infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Helicobacter infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Lymphogranuloma venereum						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Orchitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Pharyngeal chlamydia infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Postoperative wound infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Primary syphilis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pulpitis dental						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Skin infection						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Staphylococcal skin infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Ureaplasma infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Varicella						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abscess limb						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod infestation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Asymptomatic bacteriuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial diarrhoea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Bacterial rhinitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vaginosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Bronchitis viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Chest wall abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic sinusitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Conjunctivitis viral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cutaneous blastomycosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Dermatophytosis of nail						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Device related infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Diarrhoea infectious						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear infection bacterial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Enterobiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterovirus infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Epiglottitis obstructive						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erysipelas						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Erythema migrans						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
External ear cellulitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gastroenteritis Escherichia coli						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Genital herpes simplex						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genitourinary tract infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gingival abscess						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infectious mononucleosiss						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Labyrinthitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lice infestation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Mycoplasma infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal candidiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ophthalmic herpes zoster						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Penile infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pericoroniti s						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Perirectal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peritonsillar abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pharyngitis bacterial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Proctitis chlamydial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pulmonary tuberculosis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal abscess						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Schistosomiasis cutaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sialoadenitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin bacterial infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Syphilis genital						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea capitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tinea cruris						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea pedis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tracheobronchitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Trichomoniasis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Viral rash						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rhinitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Vulvovaginal mycotic infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	21/ 84 (25%)	24/ 98 (24%)	1.0278 (0.5232, 2.0190) /0.937	0.5102 (-12.0689, 13.0893) /0.937	1.0208 (0.6142, 1.6966) /0.937	0.355
35 - <50	30/154 (19%)	44/143 (31%)	0.5444 (0.3191, 0.9285) /0.026	-11.2887 (-21.1046, -1.4729) /0.024	0.6331 (0.4225, 0.9487) /0.027	
>=50	20/ 89 (22%)	25/ 86 (29%)	0.7072 (0.3578, 1.3980) /0.319	-6.5979 (-19.5323, 6.3366) /0.317	0.7730 (0.4652, 1.2845) /0.320	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
<35	9/ 84 (11%)	5/ 98 (5%)				
35 - <50	11/154 (7%)	12/143 (8%)				
>=50	5/ 89 (6%)	7/ 86 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	4/ 84 (5%)	6/ 98 (6%)	0.7667 (0.2089, 2.8135) /0.689	-1.3605 (-7.9385, 5.2174) /0.685	0.7778 (0.2271, 2.6640) /0.689	0.101
35 - <50	1/154 (<1%)	10/143 (7%)	0.0869 (0.0110, 0.6880) /0.021	-6.3437 (-10.7119, -1.9755) /0.004	0.0929 (0.0120, 0.7163) /0.023	
>=50	3/ 89 (3%)	4/ 86 (5%)	0.7151 (0.1553, 3.2933) /0.667	-1.2804 (-7.1000, 4.5393) /0.666	0.7247 (0.1671, 3.1435) /0.667	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dyspepsia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Abdominal pain						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids						
<35	0/ 84	6/ 98 (6%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Toothache						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				
Vomiting						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
<35	0/ 84	0/ 98				
35 - <50	3/154 (2%)	1/143 (<1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				
Constipation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain upper						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Abdominal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Abdominal pain lower						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Anal fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Inguinal hernia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dry mouth						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Irritable bowel syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective gingivitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Rectal discharge						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Abdominal hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal tenderness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Anal fissure						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Angular cheilitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cheilitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Crohn's disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dental caries						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Enterocolitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Food poisoning						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Gastric disorder						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Gingival hypertrophy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Glossitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematemesis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Haematochezi						
^a <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids 1 haemorrhage						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Haemorrhoids thrombosed						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hiatus hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Hypertrophic anal papilla						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Intestinal polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Large intestine polyp						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Mouth ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophagitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Oroantral fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Perianal erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontal disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Proctalgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tongue ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	11/ 84 (13%)	20/ 98 (20%)				
35 - <50	31/154 (20%)	33/143 (23%)				
>=50	23/ 89 (26%)	26/ 86 (30%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
<35	2/ 84 (2%)	6/ 98 (6%)				
35 - <50	8/154 (5%)	11/143 (8%)				
>=50	6/ 89 (7%)	3/ 86 (3%)				
Arthralgia						
<35	0/ 84	2/ 98 (2%)				
35 - <50	8/154 (5%)	5/143 (3%)				
>=50	8/ 89 (9%)	9/ 86 (10%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	5/154 (3%)	5/143 (3%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Myalgia						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	4/143 (3%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Muscle spasms						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal chest pain						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Neck pain						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Intervertebral disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Synovial cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bursitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Exostosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Limb discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Arthritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Cervical spinal stenosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Femoroacetabular impingement						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Flank pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Groin pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Joint stiffness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Muscle tightness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Musculoskeletal stiffness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Osteonecrosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteopenia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pain in jaw						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periarthriti s						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Plantar fasciitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Scoliosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Spinal osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Temporomandibular joint syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Tenosynovitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigger finger						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	18/ 84 (21%)	16/ 98 (16%)				
35 - <50	19/154 (12%)	28/143 (20%)				
>=50	17/ 89 (19%)	20/ 86 (23%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus						
<35	5/ 84 (6%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	4/ 89 (4%)	3/ 86 (3%)				
Rash						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	3/ 89 (3%)	4/ 86 (5%)				
Alopecia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	4/ 89 (4%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	3/ 89 (3%)	2/ 86 (2%)				
Dermatitis						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acne						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	3/ 86 (3%)				
Dermal cyst						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosi s						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Night sweats						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				
Dermatitis contact						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urticaria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Dry skin						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Skin exfoliation						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Skin mass						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Androgenetic alopecia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chloasma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cold sweat						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dermatitis atopic						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug eruption						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Ecchymosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema asteatotic						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hand dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Keratosis pilaris						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lichen sclerosus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Macule						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Miliaria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nail bed inflammation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain of skin						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Penile ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Petechiae						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pigmentation disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pityriasis rosea <35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Psoriasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Purpura						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rash maculo-papular						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash morbilliform						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Rash pruritic						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin discolouration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypertrophy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Skin irritation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin swelling						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Solar dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	11/ 84 (13%)	12/ 98 (12%)				
35 - <50	24/154 (16%)	27/143 (19%)				
>=50	10/ 89 (11%)	13/ 86 (15%)				
Headache						
<35	4/ 84 (5%)	4/ 98 (4%)				
35 - <50	14/154 (9%)	17/143 (12%)				
>=50	4/ 89 (4%)	6/ 86 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dizziness						
<35	6/ 84 (7%)	4/ 98 (4%)				
35 - <50	5/154 (3%)	4/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Paraesthesia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Presyncope						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Migraine						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Somnolence						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Head discomfort						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hypoaesthesia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lethargy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Syncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Amnesia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burning sensation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Carpal tunnel syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebral infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cerebrovascular accident						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Disturbance in attention						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysarthria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Dysgeusia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperaesthesia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hypersomnia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Muscle contractions involuntary						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Periodic limb movement disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyneuropathy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	14/ 84 (17%)	13/ 98 (13%)				
35 - <50	11/154 (7%)	24/143 (17%)				
>=50	14/ 89 (16%)	18/ 86 (21%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cough						
<35	6/ 84 (7%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	12/143 (8%)				
>=50	6/ 89 (7%)	6/ 86 (7%)				
Oropharyngeal pain						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	4/ 89 (4%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Sinus congestion						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Asthma						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epistaxis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Sleep apnoea syndrome						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Productive cough						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Catarrh						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Haemoptysis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Rales						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Bronchospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry throat						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Interstitial lung disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nasal oedema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Painful respiration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pleuritic pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Respiratory disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Snoring						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	9/ 84 (11%)	17/ 98 (17%)	0.5718 (0.2403, 1.3605) /0.206	-6.6327 (-16.6302, 3.3649) /0.193	0.6176 (0.2907, 1.3122) /0.210	0.041
35 - <50	8/154 (5%)	27/143 (19%)	0.2354 (0.1031, 0.5376) /<.001	-13.6863 (-20.9959, -6.3768) /<.001	0.2751 (0.1293, 0.5856) /<.001	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	14/ 89 (16%)	14/ 86 (16%)	0.9600 (0.4278, 2.1543) /0.921	-0.5487 (-11.4158, 10.3184) /0.921	0.9663 (0.4901, 1.9053) /0.921	
Arthropod bite						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	6/143 (4%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Limb injury						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	3/ 89 (3%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Contusion						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	2/ 89 (2%)	0/ 86				
Ligament sprain						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin laceration						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Muscle strain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Arthropod sting						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Animal bite						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heat stroke						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Joint injury						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Musculoskeletal foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Vaccination complication						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Wrist fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Bone contusion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burns second degree						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Chemical burns of eye						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Concussion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Corneal abrasion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Epicondylitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Fibula fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Head injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injury corneal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lip injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Overdose						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Scapula fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sunburn						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Thermal burn						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Traumatic haematoma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ulna fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	13/ 84 (15%)	14/ 98 (14%)				
35 - <50	16/154 (10%)	21/143 (15%)				
>=50	6/ 89 (7%)	9/ 86 (10%)				
Insomnia						
<35	4/ 84 (5%)	4/ 98 (4%)				
35 - <50	4/154 (3%)	11/143 (8%)				
>=50	3/ 89 (3%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety						
<35	6/ 84 (7%)	5/ 98 (5%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Depression						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep disorder						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Abnormal dreams						
<35	0/ 84	0/ 98				
35 - <50	0/154	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Libido decreased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Panic attack						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Drug abuse						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Major depression						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with mixed anxiety and depressed mood						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Agoraphobia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Emotional distress						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Loss of libido						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Mood swings						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Post-traumatic stress disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Restlessness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Stress						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	5/ 84 (6%)	8/ 98 (8%)				
35 - <50	8/154 (5%)	16/143 (11%)				
>=50	5/ 89 (6%)	6/ 86 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				
Weight increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Blood cholesterol increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lipase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Weight decreased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin unconjugated increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Blood triglycerides increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
CD4 lymphocytes decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Campylobacter test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydia test positive						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Culture urine positive						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Escherichia test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Haemoglobin increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Intraocular pressure increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Parasite stool test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Transaminases increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D decreased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
White blood cell count decreased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	3/ 84 (4%)	9/ 98 (9%)				
35 - <50	8/154 (5%)	3/143 (2%)				
>=50	5/ 89 (6%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
<35	0/ 84	4/ 98 (4%)				
35 - <50	2/154 (1%)	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Prostatomegaly						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular cyst						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Atrophic vulvovaginitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanoposthitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Benign prostatic hyperplasia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Breast pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Genital erythema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Menorrhagia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile burning sensation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Penile discharge						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Priapism						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prostatitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Testicular mass						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Testicular torsion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testis discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Uterine polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	3/154 (2%)	7/143 (5%)				
>=50	3/ 89 (3%)	6/ 86 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Skin papilloma						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Acrochordon						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Basal cell carcinoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibroma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Lipoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipoma of breast						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethral papilloma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	4/ 84 (5%)	3/ 98 (3%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	6/ 89 (7%)	7/ 86 (8%)				
Hypertension						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	4/ 89 (4%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flushing						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Haematoma						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure inadequately controlled						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hot flush						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypotension						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Peripheral coldness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Thrombophlebitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Varicose vein						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	5/154 (3%)	5/143 (3%)				
>=50	1/ 89 (1%)	7/ 86 (8%)				
Blepharitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blepharospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cataract						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chalazion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Diplopia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry eye						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Eye pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Eyelid oedema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glaucoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Iritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mydriasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ocular hyperaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Ulcerative keratitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vision blurred						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Vitreous floaters						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<35	1/ 84 (1%)	6/ 98 (6%)	0.1847 (0.0218, 1.5666) /0.122	-4.9320 (-10.2149, 0.3509) /0.067	0.1944 (0.0239, 1.5829) /0.126	0.546
35 - <50	4/154 (3%)	6/143 (4%)	0.6089 (0.1683, 2.2035) /0.450	-1.5984 (-5.7347, 2.5379) /0.449	0.6190 (0.1783, 2.1489) /0.450	
>=50	1/ 89 (1%)	4/ 86 (5%)	0.2330 (0.0255, 2.1275) /0.197	-3.5276 (-8.4879, 1.4328) /0.163	0.2416 (0.0275, 2.1182) /0.200	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Renal colic						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition urgency						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Nocturia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pollakiuria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Haematuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocyturia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Micturition disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nephropathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureterolithiasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethral disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	2/154 (1%)	5/143 (3%)				
>=50	5/ 89 (6%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Vertigo						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerumen impaction						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	2/ 89 (2%)	0/ 86				
Ear discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Excessive cerumen production						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Deafness neurosensory						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Eustachian tube dysfunction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoacusis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tympanic membrane perforation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	7/154 (5%)	2/143 (1%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	0/143				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Hypersensitivity						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Drug hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	1/ 84 (1%)	4/ 98 (4%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	3/ 89 (3%)	6/ 86 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Vitamin D deficiency						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Obesity						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Cachexia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gluten sensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Gout						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hyperlipasemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	3/143 (2%)				
>=50	3/ 89 (3%)	2/ 86 (2%)				
Palpitations						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tachycardia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Acute myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Angina pectoris						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Atrial fibrillation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac aneurysm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Ventricular extrasystoles						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	2/ 89 (2%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymph node pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lymphadenopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Neutropenia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial septal defect						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Benign familial pemphigus						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Type V hyperlipidaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Hypogonadism						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Goitre						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hepatomegaly						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Jaundice						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with
 (1) significant difference in occurrences between treatment arms on the study level (p<0.05)
 (2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.
 OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.
 Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Stress at work						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
Female	61/ 73 (84%)	66/ 75 (88%)				
Male	242/254 (95%)	244/252 (97%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	54/ 73 (74%)	55/ 75 (73%)				
Male	225/254 (89%)	220/252 (87%)				
Injection site pain						
Female	48/ 73 (66%)	51/ 75 (68%)				
Male	214/254 (84%)	205/252 (81%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	10/ 73 (14%)	18/ 75 (24%)	0.5026 (0.2144, 1.1784) /0.114	-10.3014 (-22.7768, 2.1740) /0.106	0.5708 (0.2827, 1.1525) /0.118	0.594
Male	20/254 (8%)	44/252 (17%)	0.4040 (0.2307, 0.7078) /0.002	-9.5863 (-15.3256, -3.8470) /0.001	0.4510 (0.2738, 0.7428) /0.002	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
Female	2/ 73 (3%)	3/ 75 (4%)				
Male	24/254 (9%)	26/252 (10%)				
Pyrexia						
Female	3/ 73 (4%)	2/ 75 (3%)				
Male	18/254 (7%)	32/252 (13%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
Female	9/ 73 (12%)	11/ 75 (15%)				
Male	14/254 (6%)	17/252 (7%)				
Injection site swelling						
Female	10/ 73 (14%)	6/ 75 (8%)				
Male	13/254 (5%)	13/252 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
Female	1/ 73 (1%)	1/ 75 (1%)	1.0278 (0.0631, 16.7455) /0.985	0.0365 (-3.6848, 3.7578) /0.985	1.0274 (0.0655, 16.1197) /0.985	0.415
Male	7/254 (3%)	23/252 (9%)	0.2822 (0.1188, 0.6701) /0.004	-6.3711 (-10.4572, -2.2850) /0.002	0.3020 (0.1319, 0.6910) /0.005	
Injection site pruritus						
Female	2/ 73 (3%)	8/ 75 (11%)				
Male	6/254 (2%)	8/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
Female	5/ 73 (7%)	3/ 75 (4%)				
Male	9/254 (4%)	4/252 (2%)				
Injection site erythema						
Female	2/ 73 (3%)	5/ 75 (7%)				
Male	7/254 (3%)	7/252 (3%)				
Chills						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	11/254 (4%)	7/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
Female	0/ 73	7/ 75 (9%)				
Male	5/254 (2%)	5/252 (2%)				
Injection site bruising						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	7/254 (3%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
Female	1/ 73 (1%)	0/ 75				
Male	5/254 (2%)	7/252 (3%)				
Injection site warmth						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	3/254 (1%)	4/252 (2%)				
Pain						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	8/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	7/252 (3%)				
Chest pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	3/252 (1%)				
Discomfort						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Feeling hot						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Nodule						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Vessel puncture site haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Gait disturbance						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Injection site discolouration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Injection site papule						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Chronic fatigue syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Induration						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Inflammation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site discharge						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site fibrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Injection site hypersensitivity						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site necrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Oedema peripheral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sluggishness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Thirst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Xerosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	32/ 73 (44%)	43/ 75 (57%)	0.5808 (0.3031, 1.1131) /0.102	-13.4977 (-29.4618, 2.4663) /0.097	0.7646 (0.5525, 1.0581) /0.105	0.351
Male	144/254 (57%)	158/252 (63%)	0.7788 (0.5455, 1.1119) /0.169	-6.0055 (-14.5368, 2.5258) /0.168	0.9042 (0.7833, 1.0439) /0.169	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	8/ 73 (11%)	11/ 75 (15%)				
Male	40/254 (16%)	38/252 (15%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	4/ 73 (5%)	11/ 75 (15%)	0.3373 (0.1022, 1.1130) /0.074	-9.1872 (-18.7454, 0.3709) /0.060	0.3736 (0.1246, 1.1202) /0.079	0.245
Male	31/254 (12%)	42/252 (17%)	0.6951 (0.4212, 1.1470) /0.155	-4.4619 (-10.5757, 1.6518) /0.153	0.7323 (0.4763, 1.1259) /0.156	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	2/ 73 (3%)	5/ 75 (7%)	0.3944 (0.0740, 2.1007) /0.276	-3.9269 (-10.7013, 2.8474) /0.256	0.4110 (0.0823, 2.0515) /0.278	0.835
Male	9/254 (4%)	18/252 (7%)	0.4776 (0.2103, 1.0842) /0.077	-3.5996 (-7.5085, 0.3094) /0.071	0.4961 (0.2272, 1.0832) /0.079	
Pharyngitis						
Female	2/ 73 (3%)	3/ 75 (4%)				
Male	9/254 (4%)	15/252 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
Female	0/ 73	0/ 75				
Male	7/254 (3%)	16/252 (6%)				
Bronchitis						
Female	3/ 73 (4%)	3/ 75 (4%)				
Male	8/254 (3%)	8/252 (3%)				
Influenza						
Female	3/ 73 (4%)	4/ 75 (5%)				
Male	6/254 (2%)	7/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
Female	0/ 73	0/ 75				
Male	9/254 (4%)	9/252 (4%)				
Sinusitis						
Female	0/ 73	1/ 75 (1%)				
Male	7/254 (3%)	8/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	5/254 (2%)	7/252 (3%)				
Chlamydial infection						
Female	0/ 73	0/ 75				
Male	8/254 (3%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	3/254 (1%)	5/252 (2%)				
Viral infection						
Female	0/ 73	2/ 75 (3%)				
Male	7/254 (3%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	8/252 (3%)				
Respiratory tract infection						
Female	3/ 73 (4%)	2/ 75 (3%)				
Male	2/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	6/252 (2%)				
Conjunctivitis						
Female	0/ 73	3/ 75 (4%)				
Male	3/254 (1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				
Oral herpes						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	1/254 (<1%)	5/252 (2%)				
Rhinitis						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				
Viral upper respiratory tract infection						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	7/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Folliculitis						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Gastroenteritis viral						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Herpes zoster						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	4/252 (2%)				
Ear infection						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Furuncle						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Herpes simplex						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Lower respiratory tract infection						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal gonococcal infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Pneumonia						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	4/252 (2%)				
Urethritis gonococcal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Gingivitis						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma genitalium infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	3/252 (1%)				
Onychomycosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	2/252 (<1%)				
Acarodermatitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				
Body tinea						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Diverticulitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Genital herpes						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Otitis externa						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Paronychia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotonsillitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Secondary syphilis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Tracheitis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Vaginal infection						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Cystitis						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Epididymitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia urinary tract infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Helicobacter infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Injection site abscess						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				
Laryngitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranuloma venereum						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Molluscum contagiosum						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Orchitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Pharyngeal chlamydia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Postoperative wound infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Pulpitis dental						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Staphylococcal skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Ureaplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Varicella						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Abscess limb						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod infestation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Asymptomatic bacteriuria						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial diarrhoea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
 Bacterial rhinitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vaginosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Bronchitis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chest wall abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic sinusitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Conjunctivitis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cutaneous blastomycosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Dermatophytosis of nail						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Device related infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Diarrhoea infectious						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection bacterial						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Enterobiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterovirus infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Epiglottitis obstructive						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Erysipelas						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erythema migrans						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Escherichia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

External ear cellulitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastritis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Genital candidiasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Genitourinary tract infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Groin abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infectious mononucleosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Labyrinthitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lice infestation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Mycoplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ophthalmic herpes zoster						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Penile infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pericoroniti s						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Perirectal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peritonsillar abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pharyngitis bacterial						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Proctitis chlamydial						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pulmonary tuberculosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Schistosomiasis cutaneous						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sialoadenitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin bacterial infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Syphilis genital						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea capitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tinea cruris						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tinea pedis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheobronchitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Trichomoniasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Viral rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rhinitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Vulvovaginal mycotic infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	9/ 73 (12%)	15/ 75 (20%)	0.5625 (0.2291, 1.3812) /0.209	-7.6712 (-19.4538, 4.1114) /0.202	0.6164 (0.2880, 1.3194) /0.213	0.549
Male	62/254 (24%)	78/252 (31%)	0.7204 (0.4870, 1.0656) /0.101	-6.5429 (-14.3201, 1.2342) /0.099	0.7886 (0.5934, 1.0480) /0.102	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	23/254 (9%)	22/252 (9%)				
Nausea						
Female	0/ 73	4/ 75 (5%)	<0.0001 (<0.0001, -) />0.999	-7.4895 (-31.4579, 16.4789) /0.540	<0.0001 (<0.0001, -) />0.999	0.088
Male	8/254 (3%)	16/252 (6%)	0.4797 (0.2015, 1.1418) /0.097	-3.1996 (-6.8979, 0.4987) /0.090	0.4961 (0.2162, 1.1383) /0.098	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
Female	0/ 73	1/ 75 (1%)				
Male	6/254 (2%)	7/252 (3%)				
Abdominal pain						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	3/254 (1%)	4/252 (2%)				
Haemorrhoids						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	8/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	6/252 (2%)				
Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	6/252 (2%)				
Vomiting						
Female	0/ 73	2/ 75 (3%)				
Male	6/254 (2%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
Female	1/ 73 (1%)	0/ 75				
Male	4/254 (2%)	3/252 (1%)				
Constipation						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	6/252 (2%)				
Abdominal pain upper						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Anogenital dysplasia						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Gastritis						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	1/252 (<1%)				
Anal fistula						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Inguinal hernia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Colitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry mouth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Gingival pain						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Noninfective gingivitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Rectal haemorrhage						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal hernia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Abdominal tenderness						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal fissure						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Angular cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Crohn's disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dental caries						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterocolitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Food poisoning						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastric disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastrointestinal disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival hypertrophy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gingival ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Glossitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematemesis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Haematochezi ^a						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal						
1						
haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Haemorrhoids thrombosed						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hiatus hernia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hypertrophic anal papilla						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Intestinal polyp						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine polyp						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Mouth ulceration						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophagitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Oroantral fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pancreatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Perianal erythema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Periodontal disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Proctalgia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tongue ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tooth disorder						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	14/ 73 (19%)	17/ 75 (23%)				
Male	51/254 (20%)	62/252 (25%)				
Back pain						
Female	4/ 73 (5%)	6/ 75 (8%)				
Male	12/254 (5%)	14/252 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
Female	4/ 73 (5%)	4/ 75 (5%)				
Male	12/254 (5%)	12/252 (5%)				
Pain in extremity						
Female	0/ 73	1/ 75 (1%)				
Male	8/254 (3%)	12/252 (5%)				
Myalgia						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	8/254 (3%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	1/ 73 (1%)	0/ 75				
Male	7/254 (3%)	5/252 (2%)				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	7/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	2/254 (<1%)	2/252 (<1%)				
Neck pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	4/254 (2%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	3/252 (1%)				
Intervertebral disc protrusion						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
Female	2/ 73 (3%)	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Rotator cuff syndrome						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Tendonitis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovial cyst						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Bursitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Exostosis						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Limb discomfort						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Arthritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Arthropathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical spinal stenosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Costochondritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Femoroacetabular impingement						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Flank pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Groin pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Joint stiffness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Muscle tightness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Musculoskeletal stiffness						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Osteonecrosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Osteopenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in jaw						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Periarthriti s						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Plantar fasciitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scoliosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Spinal osteoarthritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Synovitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tendon disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Trigger finger						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	11/ 73 (15%)	13/ 75 (17%)				
Male	43/254 (17%)	51/252 (20%)				
Pruritus						
Female	1/ 73 (1%)	3/ 75 (4%)				
Male	9/254 (4%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with (1) significant difference in occurrences between treatment arms on the study level (p<0.05) (2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	5/254 (2%)	8/252 (3%)				
Eczema						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	3/254 (1%)	4/252 (2%)				
Alopecia						
Female	3/ 73 (4%)	1/ 75 (1%)				
Male	3/254 (1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	4/254 (2%)	2/252 (<1%)				
Dermatitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				
Acne						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermal cyst						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Hyperhidrosi s						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	3/252 (1%)				
Night sweats						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Dermatitis contact						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Urticaria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry skin						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Rash erythematous						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Skin exfoliation						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Skin mass						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Androgenetic alopecia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chloasma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Cold sweat						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dermatitis atopic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug eruption						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Ecchymosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eczema asteatotic						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Granuloma annulare						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hand dermatitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Keratosis pilaris						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Lichen sclerosus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macule						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Miliaria						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nail bed inflammation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain of skin						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Penile ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Petechiae						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pigmentation disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pityriasis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pityriasis rosea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Psoriasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Purpura						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rash morbilliform						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash pruritic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rash vesicular						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin discolouration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin hypertrophy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin irritation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Skin swelling						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Solar dermatitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Nervous system disorders						
Any Event						
Female	4/ 73 (5%)	11/ 75 (15%)				
Male	41/254 (16%)	41/252 (16%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
Female	3/ 73 (4%)	6/ 75 (8%)				
Male	19/254 (7%)	21/252 (8%)				
Dizziness						
Female	0/ 73	4/ 75 (5%)				
Male	12/254 (5%)	6/252 (2%)				
Paraesthesia						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
Female	0 / 73	2 / 75 (3%)				
Male	1/254 (<1%)	2/252 (<1%)				
Migraine						
Female	0 / 73	0 / 75				
Male	1/254 (<1%)	2/252 (<1%)				
Sciatica						
Female	0 / 73	0 / 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Somnolence						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Head discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Hypoaesthesia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Syncope						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Tension headache						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Burning sensation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cerebral infarction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebrovascular accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cervical radiculopathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dysarthria						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Dysgeusia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperaesthesia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypersomnia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypertonia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Neuropathy peripheral						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Polyneuropathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculopathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	9/ 73 (12%)	13/ 75 (17%)				
Male	30/254 (12%)	42/252 (17%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	4/ 73 (5%)	6/ 75 (8%)				
Male	11/254 (4%)	15/252 (6%)				
Oropharyngeal pain						
Female	5/ 73 (7%)	3/ 75 (4%)				
Male	2/254 (<1%)	8/252 (3%)				
Rhinitis allergic						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	6/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	5/252 (2%)				
Nasal congestion						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	3/252 (1%)				
Asthma						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epistaxis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Dyspnoea						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Catarrh						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Haemoptysis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Rales						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Rhinorrhoea						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Dry throat						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Interstitial lung disease						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nasal oedema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nasal septum deviation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Painful respiration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pleuritic pain						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Respiratory tract congestion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	3/ 73 (4%)	11/ 75 (15%)	0.2494 (0.0666, 0.9342) /0.039	-10.5571 (-19.7680, -1.3462) /0.025	0.2802 (0.0815, 0.9637) /0.044	0.237
Male	28/254 (11%)	47/252 (19%)	0.5404 (0.3262, 0.8951) /0.017	-7.6272 (-13.7885, -1.4658) /0.015	0.5911 (0.3829, 0.9125) /0.018	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
Female	0/ 73	3/ 75 (4%)				
Male	2/254 (<1%)	5/252 (2%)				
Exposure to communicable disease						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
Female	0/ 73	0/ 75				
Male	6/254 (2%)	3/252 (1%)				
Contusion						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	3/252 (1%)				
Ligament sprain						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin laceration						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Muscle strain						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Arthropod sting						
Female	0/ 73	3/ 75 (4%)				
Male	0/254	0/252				
Rib fracture						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Heat stroke						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Joint injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Musculoskeletal foreign body						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Vaccination complication						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Wrist fracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Bone contusion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burns second degree						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chemical burns of eye						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Concussion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Corneal abrasion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Fall						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Fibula fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Head injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injury corneal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Lip injury						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nail injury						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Procedural pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Scapula fracture						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Thermal burn						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Traumatic haematoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ulna fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Psychiatric disorders						
Any Event						
Female	1/ 73 (1%)	7/ 75 (9%)				
Male	34/254 (13%)	37/252 (15%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
Female	1/ 73 (1%)	3/ 75 (4%)				
Male	10/254 (4%)	15/252 (6%)				
Anxiety						
Female	0/ 73	0/ 75				
Male	9/254 (4%)	7/252 (3%)				
Depression						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	5/252 (2%)				
Abnormal dreams						
Female	0/ 73	0/ 75				
Male	0/254	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Libido decreased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Nightmare						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Adjustment disorder with depressed mood						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Irritability						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Major depression						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Adjustment disorder with mixed anxiety and depressed mood						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Agoraphobia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Emotional distress						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Loss of libido						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Nervousness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Post-traumatic stress disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Restlessness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Stress						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Investigations						
Any Event						
Female	0/ 73	6/ 75 (8%)				
Male	18/254 (7%)	24/252 (10%)				
Body temperature increased						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Alanine aminotransferase increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Blood pressure increased						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Blood glucose increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Low density lipoprotein increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Aspartate aminotransferase increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blood bilirubin unconjugated increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Blood triglycerides increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
CD4 lymphocytes decreased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Campylobacter test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Creatinine renal clearance decreased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Culture urine positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Escherichia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Haemoglobin increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intraocular pressure increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Parasite stool test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Shigella test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Transaminases increased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
White blood cell count decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	4/ 73 (5%)	1/ 75 (1%)				
Male	12/254 (5%)	14/252 (6%)				
Erectile dysfunction						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prostatomegaly						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Testicular cyst						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Balanoposthitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Breast cyst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Breast pain						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Genital erythema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Menorrhagia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile burning sensation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Penile discharge						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Priapism						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Prostatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Testicular pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular torsion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Testis discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Uterine polyp						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Vaginal discharge						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	8/254 (3%)	17/252 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	7/252 (3%)				
Skin papilloma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Acrochordon						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Basal cell carcinoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Fibroma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lipoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Lipoma of breast						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral papilloma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Uterine leiomyoma						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	3/ 73 (4%)	5/ 75 (7%)				
Male	10/254 (4%)	8/252 (3%)				
Hypertension						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	7/254 (3%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flushing						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Peripheral venous disease						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure inadequately controlled						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Hot flush						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypotension						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Peripheral coldness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Thrombophlebitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicose vein						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eye disorders						
Any Event						
Female	3/ 73 (4%)	3/ 75 (4%)				
Male	4/254 (2%)	13/252 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	3/252 (1%)				
Conjunctivitis allergic						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Retinal detachment						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blepharospasm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cataract						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chalazion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diplopia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Dry eye						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Eye pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid cyst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eyelid oedema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Glaucoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Mydriasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ocular hyperaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Ulcerative keratitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Vision blurred						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Vitreous floaters						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
Female	2/ 73 (3%)	4/ 75 (5%)	0.5000 (0.0887, 2.8174) /0.432	-2.5936 (-8.9089, 3.7216) /0.421	0.5137 (0.0970, 2.7193) /0.433	0.670
Male	4/254 (2%)	12/252 (5%)	0.3200 (0.1018, 1.0059) /0.051	-3.1871 (-6.2297, -0.1445) /0.040	0.3307 (0.1081, 1.0116) /0.052	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	2/252 (<1%)				
Renal colic						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Micturition urgency						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nocturia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Pollakiuria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Haematuria						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocyturia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Micturition disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nephrolithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Ureterolithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urethral disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Ear and labyrinth disorders						
Any Event						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	7/254 (3%)	10/252 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				
Vertigo						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Cerumen impaction						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Excessive cerumen production						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deafness neurosensory						
Female	0 / 73	0 / 75				
Male	0 / 254	1 / 252 (<1%)				
Ear pain						
Female	0 / 73	1 / 75 (1%)				
Male	0 / 254	0 / 252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypoacusis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Immune system disorders						
Any Event						
Female	2/ 73 (3%)	3/ 75 (4%)				
Male	9/254 (4%)	6/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	5/254 (2%)	3/252 (1%)				
Hypersensitivity						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				
Food allergy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Metabolism and nutrition disorders						
Any Event						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	5/254 (2%)	9/252 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Vitamin D deficiency						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Obesity						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Cachexia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gluten sensitivity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gout						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hyperglycaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasae mia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hypokalaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	6/252 (2%)				
Palpitations						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tachycardia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angina pectoris						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Atrial fibrillation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac aneurysm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ventricular extrasystoles						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				
Iron deficiency anaemia						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Lymph node pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Lymphadenopathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Neutropenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Atrial septal defect						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign familial pemphigus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hydrocele						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type V hyperlipidaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Endocrine disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Goitre						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Cholelithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatomegaly						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Jaundice						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Social circumstances						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Menopause						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stress at work						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Abortion spontaneous						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
White	221/238 (93%)	244/256 (95%)				
Non-White	82/ 89 (92%)	66/ 71 (93%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	206/238 (87%)	221/256 (86%)				
Non-White	73/ 89 (82%)	54/ 71 (76%)				
Injection site pain						
White	192/238 (81%)	208/256 (81%)				
Non-White	70/ 89 (79%)	48/ 71 (68%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
White	20/238 (8%)	41/256 (16%)	0.4811 (0.2729, 0.8480) /0.011	-7.6123 (-13.3225, -1.9020) /0.009	0.5247 (0.3168, 0.8691) /0.012	0.454
Non-White	10/ 89 (11%)	21/ 71 (30%)	0.3014 (0.1311, 0.6927) /0.005	-18.3415 (-30.8213, -5.8617) /0.004	0.3799 (0.1914, 0.7539) /0.006	

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
White	21/238 (9%)	26/256 (10%)				
Non-White	5/ 89 (6%)	3/ 71 (4%)				
Pyrexia						
White	17/238 (7%)	31/256 (12%)				
Non-White	4/ 89 (4%)	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
White	18/238 (8%)	23/256 (9%)				
Non-White	5/ 89 (6%)	5/ 71 (7%)				
Injection site swelling						
White	13/238 (5%)	10/256 (4%)				
Non-White	10/ 89 (11%)	9/ 71 (13%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	2/238 (<1%)	19/256 (7%)	0.1057 (0.0244, 0.4589) /0.003	-6.5815 (-9.9955, -3.1675) /<.001	0.1132 (0.0267, 0.4809) /0.003	0.014
Non-White	6/ 89 (7%)	5/ 71 (7%)	0.9542 (0.2789, 3.2648) /0.940	-0.3007 (-8.2099, 7.6085) /0.941	0.9573 (0.3046, 3.0086) /0.940	
Injection site pruritus						
White	4/238 (2%)	12/256 (5%)				
Non-White	4/ 89 (4%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
White	11/238 (5%)	7/256 (3%)				
Non-White	3/ 89 (3%)	0/ 71				
Injection site erythema						
White	8/238 (3%)	11/256 (4%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Chills						
White	9/238 (4%)	6/256 (2%)				
Non-White	3/ 89 (3%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
White	4/238 (2%)	8/256 (3%)				
Non-White	1/ 89 (1%)	4/ 71 (6%)				
Injection site bruising						
White	8/238 (3%)	5/256 (2%)				
Non-White	0/ 89	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
White	4/238 (2%)	7/256 (3%)				
Non-White	2/ 89 (2%)	0/ 71				
Injection site warmth						
White	3/238 (1%)	3/256 (1%)				
Non-White	2/ 89 (2%)	3/ 71 (4%)				
Pain						
White	3/238 (1%)	5/256 (2%)				
Non-White	0/ 89	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
White	1/238 (<1%)	8/256 (3%)				
Non-White	0/ 89	1/ 71 (1%)				
Chest pain						
White	3/238 (1%)	4/256 (2%)				
Non-White	1/ 89 (1%)	0/ 71				
Discomfort						
White	3/238 (1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
White	3/238 (1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Feeling hot						
White	2/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site anaesthesia						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Nodule						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral swelling						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Vessel puncture site haematoma						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Gait disturbance						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site papule						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chronic fatigue syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Induration						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Inflammation						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site discharge						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site fibrosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site hypersensitivity						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site necrosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site rash						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Oedema peripheral						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Sluggishness						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Thirst						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Xerosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	133/238 (56%)	161/256 (63%)	0.7474 (0.5213, 1.0715) /0.113	-7.0083 (-15.6578, 1.6412) /0.112	0.8886 (0.7671, 1.0292) /0.115	0.834
Non-White	43/ 89 (48%)	40/ 71 (56%)	0.7245 (0.3871, 1.3558) /0.313	-8.0234 (-23.5435, 7.4967) /0.311	0.8576 (0.6373, 1.1539) /0.310	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	41/238 (17%)	45/256 (18%)				
Non-White	7/ 89 (8%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	21/238 (9%)	36/256 (14%)	0.5914 (0.3345, 1.0457) /0.071	-5.2390 (-10.8174, 0.3395) /0.066	0.6275 (0.3774, 1.0432) /0.072	0.912
Non-White	14/ 89 (16%)	17/ 71 (24%)	0.5929 (0.2693, 1.3053) /0.194	-8.2133 (-20.6931, 4.2664) /0.197	0.6570 (0.3482, 1.2396) /0.195	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
White	9/238 (4%)	20/256 (8%)	0.4638 (0.2068, 1.0398) /0.062	-4.0310 (-8.1151, 0.0531) /0.053	0.4840 (0.2249, 1.0419) /0.064	0.924
Non-White	2/ 89 (2%)	3/ 71 (4%)	0.5211 (0.0847, 3.2067) /0.482	-1.9782 (-7.5797, 3.6233) /0.489	0.5318 (0.0913, 3.0968) /0.482	
Pharyngitis						
White	8/238 (3%)	16/256 (6%)				
Non-White	3/ 89 (3%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
White	6/238 (3%)	11/256 (4%)				
Non-White	1/ 89 (1%)	5/ 71 (7%)				
Bronchitis						
White	11/238 (5%)	8/256 (3%)				
Non-White	0/ 89	3/ 71 (4%)				
Influenza						
White	7/238 (3%)	7/256 (3%)				
Non-White	2/ 89 (2%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
White	6/238 (3%)	6/256 (2%)				
Non-White	3/ 89 (3%)	3/ 71 (4%)				
Sinusitis						
White	6/238 (3%)	9/256 (4%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
White	5/238 (2%)	8/256 (3%)				
Non-White	1/ 89 (1%)	0/ 71				
Chlamydial infection						
White	6/238 (3%)	4/256 (2%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
White	4/238 (2%)	5/256 (2%)				
Non-White	0/ 89	4/ 71 (6%)				
Viral infection						
White	4/238 (2%)	5/256 (2%)				
Non-White	3/ 89 (3%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
White	3/238 (1%)	8/256 (3%)				
Non-White	1/ 89 (1%)	0/ 71				
Respiratory tract infection						
White	5/238 (2%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
White	4/238 (2%)	5/256 (2%)				
Non-White	0/ 89	2/ 71 (3%)				
Conjunctivitis						
White	3/238 (1%)	5/256 (2%)				
Non-White	0/ 89	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
White	2/238 (<1%)	4/256 (2%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Oral herpes						
White	2/238 (<1%)	7/256 (3%)				
Non-White	0/ 89	0/ 71				
Rhinitis						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
White	4/238 (2%)	3/256 (1%)				
Non-White	0/ 89	2/ 71 (3%)				
Viral upper respiratory tract infection						
White	1/238 (<1%)	4/256 (2%)				
Non-White	1/ 89 (1%)	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Gastroenteritis viral						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Herpes zoster						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
White	1/238 (<1%)	5/256 (2%)				
Non-White	0/ 89	0/ 71				
Ear infection						
White	1/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Furuncle						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Herpes simplex						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
White	1/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Lower respiratory tract infection						
White	0/238	1/256 (<1%)				
Non-White	4/ 89 (4%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Pneumonia						
White	0/238	1/256 (<1%)				
Non-White	2/ 89 (2%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
White	0/238	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Urethritis gonococcal						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Gingivitis						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma genitalium infection						
White	0/238	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Onychomycosis						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
White	0/238	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Acarodermatitis						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Body tinea						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cellulitis						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Diverticulitis						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Genital herpes						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Otitis externa						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Paronychia						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotonsillitis						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Secondary syphilis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	2/ 71 (3%)				
Tracheitis						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Vaginal infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Acute hepatitis B						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Cystitis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Epididymitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Helicobacter infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site abscess						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Laryngitis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphogranuloma venereum						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Molluscum contagiosum						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Orchitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pharyngeal chlamydia infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Postoperative wound infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pulpitis dental						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella infection						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Skin infection						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Staphylococcal skin infection						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ureaplasma infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Varicella						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Abscess limb						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod infestation						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Asymptomatic bacteriuria						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial diarrhoea						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
 Bacterial rhinitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vaginosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Bronchitis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chest wall abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic sinusitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Conjunctivitis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cutaneous blastomycosis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Dermatophytosis of nail						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Device related infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Diarrhoea infectious						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection bacterial						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Enterobiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterovirus infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Epiglottitis obstructive						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Erysipelas						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erythema migrans						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Escherichia infection						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

External ear cellulitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Gastritis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis Escherichia coli						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Genital candidiasis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Genitourinary tract infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Groin abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infectious mononucleosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Labyrinthitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lice infestation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Mycoplasma infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal candidiasis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Ophthalmic herpes zoster						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Penile infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pericoroniti s						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Perirectal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peritonsillar abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pharyngitis bacterial						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Proctitis chlamydial						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pulmonary tuberculosis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Schistosomiasis cutaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sialoadenitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin bacterial infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Subcutaneous abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Syphilis genital						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea capitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Tinea cruris						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tinea pedis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheobronchitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Trichomoniasis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Viral rash						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rhinitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vulvovaginal mycotic infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	55/238 (23%)	78/256 (30%)	0.6859 (0.4588, 1.0253) /0.066	-7.3595 (-15.1358, 0.4167) /0.064	0.7585 (0.5638, 1.0203) /0.068	0.746
Non-White	16/ 89 (18%)	15/ 71 (21%)	0.8183 (0.3729, 1.7953) /0.617	-3.1492 (-15.5510, 9.2525) /0.619	0.8509 (0.4525, 1.6003) /0.616	

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	22/238 (9%)	22/256 (9%)				
Non-White	3/ 89 (3%)	2/ 71 (3%)				
Nausea						
White	5/238 (2%)	17/256 (7%)	0.3017 (0.1095, 0.8311) /0.020	-4.5398 (-8.0926, -0.9869) /0.012	0.3164 (0.1186, 0.8441) /0.022	0.328
Non-White	3/ 89 (3%)	3/ 71 (4%)	0.7907 (0.1547, 4.0421) /0.778	-0.8546 (-6.8507, 5.1416) /0.780	0.7978 (0.1660, 3.8331) /0.778	

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
White	6/238 (3%)	6/256 (2%)				
Non-White	0/ 89	2/ 71 (3%)				
Abdominal pain						
White	5/238 (2%)	5/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Haemorrhoids						
White	1/238 (<1%)	7/256 (3%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Toothache						
White	3/238 (1%)	7/256 (3%)				
Non-White	1/ 89 (1%)	0/ 71				
Gastrooesophageal reflux disease						
White	3/238 (1%)	5/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Vomiting						
White	4/238 (2%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
White	3/238 (1%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				
Constipation						
White	1/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Abdominal pain upper						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Anogenital dysplasia						
White	3/238 (1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Gastritis						
White	0/238	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Anal fistula						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Inguinal hernia						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Colitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry mouth						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gingival pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Irritable bowel syndrome						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Noninfective gingivitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
White	0/238	0/256				
Non-White	2/ 89 (2%)	0/ 71				
Rectal haemorrhage						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Abdominal tenderness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anal fissure						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Angular cheilitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cheilitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Crohn's disease						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dental caries						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterocolitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Food poisoning						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastric disorder						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Gastrointestinal disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival hypertrophy						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Gingival ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Glossitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematemesis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haematochezi						
^a White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal 1 haemorrhage						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Haemorrhoids thrombosed						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hiatus hernia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hypertrophic anal papilla						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Intestinal polyp						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine polyp						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Mouth ulceration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophagitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Oroantral fistula						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pancreatitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Perianal erythema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Periodontal disease						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Proctalgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tongue ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tooth disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	50/238 (21%)	66/256 (26%)				
Non-White	15/ 89 (17%)	13/ 71 (18%)				
Back pain						
White	13/238 (5%)	16/256 (6%)				
Non-White	3/ 89 (3%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	11/238 (5%)	14/256 (5%)				
Non-White	5/ 89 (6%)	2/ 71 (3%)				
Pain in extremity						
White	7/238 (3%)	9/256 (4%)				
Non-White	1/ 89 (1%)	4/ 71 (6%)				
Myalgia						
White	7/238 (3%)	4/256 (2%)				
Non-White	2/ 89 (2%)	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
White	7/238 (3%)	4/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Muscle spasms						
White	0/238	5/256 (2%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Neck pain						
White	5/238 (2%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Intervertebral disc protrusion						
White	3/238 (1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
White	3/238 (1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rotator cuff syndrome						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tendonitis						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovial cyst						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Bursitis						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Exostosis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Limb discomfort						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Arthritis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Arthropathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical spinal stenosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Costochondritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Femoroacetabular impingement						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Flank pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Groin pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Joint stiffness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Muscle tightness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Musculoskeletal stiffness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Osteonecrosis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Osteopenia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in jaw						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Periarthriti s						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Plantar fasciitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Scoliosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Spinal osteoarthritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Synovitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Tendon disorder						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Trigger finger						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	36/238 (15%)	48/256 (19%)				
Non-White	18/ 89 (20%)	16/ 71 (23%)				
Pruritus						
White	5/238 (2%)	4/256 (2%)				
Non-White	5/ 89 (6%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash						
White	4/238 (2%)	8/256 (3%)				
Non-White	3/ 89 (3%)	2/ 71 (3%)				
Eczema						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	4/ 71 (6%)				
Alopecia						
White	5/238 (2%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
White	5/238 (2%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Dermatitis						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	2/ 71 (3%)				
Acne						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
White	3/238 (1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hyperhidrosi s						
White	0/238	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Night sweats						
White	3/238 (1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Dermatitis contact						
White	0/238	0/256				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Urticaria						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry skin						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Rash erythematous						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin exfoliation						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Skin mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Androgenetic alopecia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chloasma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cold sweat						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dermatitis atopic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug eruption						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Ecchymosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Eczema asteatotic						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Granuloma annulare						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hand dermatitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intertrigo						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Keratosis pilaris						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Lichen sclerosus						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macule						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Miliaria						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nail bed inflammation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain of skin						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Penile ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Petechiae						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pigmentation disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pityriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pityriasis rosea						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Psoriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Purpura						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Rash morbilliform						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash pruritic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rash vesicular						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin discolouration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin hypertrophy						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin irritation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Skin swelling						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Solar dermatitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nervous system disorders						
Any Event						
White	33/238 (14%)	42/256 (16%)				
Non-White	12/ 89 (13%)	10/ 71 (14%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Headache						
White	15/238 (6%)	22/256 (9%)				
Non-White	7/ 89 (8%)	5/ 71 (7%)				
Dizziness						
White	9/238 (4%)	7/256 (3%)				
Non-White	3/ 89 (3%)	3/ 71 (4%)				
Paraesthesia						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Migraine						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Sciatica						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Somnolence						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Head discomfort						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Hypoaesthesia						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Syncope						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Tension headache						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Amnesia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Burning sensation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cerebral infarction						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebrovascular accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cervical radiculopathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Dysarthria						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Dysgeusia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperaesthesia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hypersomnia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hypertonia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Neuropathy peripheral						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Polyneuropathy						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculopathy						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	28/238 (12%)	45/256 (18%)				
Non-White	11/ 89 (12%)	10/ 71 (14%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cough						
White	10/238 (4%)	14/256 (5%)				
Non-White	5/ 89 (6%)	7/ 71 (10%)				
Oropharyngeal pain						
White	4/238 (2%)	10/256 (4%)				
Non-White	3/ 89 (3%)	1/ 71 (1%)				
Rhinitis allergic						
White	4/238 (2%)	5/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
White	2/238 (<1%)	6/256 (2%)				
Non-White	1/ 89 (1%)	0/ 71				
Nasal congestion						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Asthma						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epistaxis						
White	1/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Sleep apnoea syndrome						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Dyspnoea						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Catarrh						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haemoptysis						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rales						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Rhinorrhoea						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dry throat						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Interstitial lung disease						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nasal oedema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nasal septum deviation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Painful respiration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pleuritic pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Respiratory tract congestion						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	27/238 (11%)	48/256 (19%)	0.5545 (0.3333, 0.9224) /0.023	-7.4055 (-13.6580, -1.1530) /0.020	0.6050 (0.3908, 0.9368) /0.024	0.280
Non-White	4/ 89 (4%)	10/ 71 (14%)	0.2871 (0.0860, 0.9581) /0.042	-9.5901 (-18.7552, -0.4251) /0.040	0.3191 (0.1044, 0.9749) /0.045	

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
White	2/238 (<1%)	7/256 (3%)				
Non-White	0/ 89	1/ 71 (1%)				
Exposure to communicable disease						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
White	4/238 (2%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				
Contusion						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Ligament sprain						
White	2/238 (<1%)	5/256 (2%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin laceration						
White	2/238 (<1%)	5/256 (2%)				
Non-White	0/ 89	0/ 71				
Muscle strain						
White	0/238	5/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Arthropod sting						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Rib fracture						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Heat stroke						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Joint injury						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Musculoskeletal foreign body						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Road traffic accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Vaccination complication						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Wrist fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Bone contusion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burns second degree						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chemical burns of eye						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Concussion						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Corneal abrasion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Fall						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Fibula fracture						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Head injury						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection related reaction						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injury corneal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint dislocation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Lip injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nail injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Procedural pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Scapula fracture						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Thermal burn						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Traumatic haematoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ulna fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Psychiatric disorders						
Any Event						
White	28/238 (12%)	31/256 (12%)				
Non-White	7/ 89 (8%)	13/ 71 (18%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
White	8/238 (3%)	8/256 (3%)				
Non-White	3/ 89 (3%)	10/ 71 (14%)				
Anxiety						
White	8/238 (3%)	7/256 (3%)				
Non-White	1/ 89 (1%)	0/ 71				
Depression						
White	3/238 (1%)	4/256 (2%)				
Non-White	0/ 89	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep disorder						
White	1/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Abnormal dreams						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Libido decreased						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nightmare						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Adjustment disorder with depressed mood						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Irritability						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Major depression						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Adjustment disorder with mixed anxiety and depressed mood						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Agoraphobia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Emotional distress						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Loss of libido						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Nervousness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Post-traumatic stress disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Restlessness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Stress						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	12/238 (5%)	23/256 (9%)				
Non-White	6/ 89 (7%)	7/ 71 (10%)				
Body temperature increased						
White	2/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Alanine aminotransferase increased						
White	1/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
White	0/238	2/256 (<1%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Blood pressure increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Blood glucose increased						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Low density lipoprotein increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Aspartate aminotransferase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood bilirubin unconjugated increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Blood triglycerides increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
CD4 lymphocytes decreased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Campylobacter test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydia test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Creatinine renal clearance decreased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Culture urine positive						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Escherichia test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Haemoglobin increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Intraocular pressure increased						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Parasite stool test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Transaminases increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
White blood cell count decreased						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	15/238 (6%)	12/256 (5%)				
Non-White	1/ 89 (1%)	3/ 71 (4%)				
Erectile dysfunction						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prostatomegaly						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Testicular cyst						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Balanoposthitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Breast cyst						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Breast pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Genital erythema						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Menorrhagia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile burning sensation						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Penile discharge						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Priapism						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Prostatitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Testicular pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular torsion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Testis discomfort						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Uterine polyp						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vaginal discharge						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	8/238 (3%)	17/256 (7%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	2/238 (<1%)	6/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Skin papilloma						
White	0/238	6/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibrous histiocytoma						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Acrochordon						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Basal cell carcinoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Fibroma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Glioblastoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lipoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Lipoma of breast						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral papilloma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Uterine leiomyoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	12/238 (5%)	10/256 (4%)				
Non-White	1/ 89 (1%)	3/ 71 (4%)				
Hypertension						
White	8/238 (3%)	4/256 (2%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flushing						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haematoma						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Peripheral venous disease						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure inadequately controlled						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Hot flush						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypotension						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Peripheral coldness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Thrombophlebitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Varicose vein						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Eye disorders						
Any Event						
White	5/238 (2%)	13/256 (5%)				
Non-White	2/ 89 (2%)	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	0/238	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Conjunctivitis allergic						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Retinal detachment						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blepharospasm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cataract						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chalazion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diplopia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dry eye						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Eye pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid cyst						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Eyelid oedema						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Glaucoma						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Mydriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ocular hyperaemia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Ulcerative keratitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vision blurred						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Vitreous floaters						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
White	3/238 (1%)	13/256 (5%)	0.2386 (0.0671, 0.8481) /0.027	-3.8176 (-6.8577, -0.7776) /0.014	0.2482 (0.0716, 0.8603) /0.028	0.249
Non-White	3/ 89 (3%)	3/ 71 (4%)	0.7907 (0.1547, 4.0421) /0.778	-0.8546 (-6.8507, 5.1416) /0.780	0.7978 (0.1660, 3.8331) /0.778	

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Renal colic						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Micturition urgency						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nocturia						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Pollakiuria						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Haematuria						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocyturia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Micturition disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nephrolithiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ureterolithiasis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Urethral disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ear and labyrinth disorders						
Any Event						
White	6/238 (3%)	7/256 (3%)				
Non-White	2/ 89 (2%)	5/ 71 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Vertigo						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cerumen impaction						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Excessive cerumen production						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deafness neurosensory						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ear pain						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Hypoacusis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Immune system disorders						
Any Event						
White	8/238 (3%)	9/256 (4%)				
Non-White	3/ 89 (3%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
White	4/238 (2%)	5/256 (2%)				
Non-White	2/ 89 (2%)	0/ 71				
Hypersensitivity						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Food allergy						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Metabolism and nutrition disorders						
Any Event						
White	3/238 (1%)	8/256 (3%)				
Non-White	3/ 89 (3%)	5/ 71 (7%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Vitamin D deficiency						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Obesity						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Cachexia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gluten sensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gout						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hyperglycaemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasae mia						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Hypokalaemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	4/238 (2%)	7/256 (3%)				
Non-White	0/ 89	0/ 71				
Palpitations						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tachycardia						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Acute myocardial infarction						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Angina pectoris						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Atrial fibrillation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiac aneurysm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ventricular extrasystoles						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	4/238 (2%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Iron deficiency anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lymph node pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Lymphadenopathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Neutropenia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Atrial septal defect						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign familial pemphigus						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Hydrocele						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type V hyperlipidaemia						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Endocrine disorders						
Any Event						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Goitre						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Cholelithiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatomegaly						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Jaundice						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Menopause						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stress at work						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	110/118 (93%)	127/135 (94%)				
Europe	154/165 (93%)	148/155 (95%)				
Rest of World	39/ 44 (89%)	35/ 37 (95%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	99/118 (84%)	109/135 (81%)				
Europe	148/165 (90%)	136/155 (88%)				
Rest of World	32/ 44 (73%)	30/ 37 (81%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	92/118 (78%)	96/135 (71%)				
Europe	138/165 (84%)	133/155 (86%)				
Rest of World	32/ 44 (73%)	27/ 37 (73%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	16/118 (14%)	32/135 (24%)	0.5049 (0.2611, 0.9765) /0.042	-10.1444 (-19.6111, -0.6777) /0.036	0.5720 (0.3311, 0.9884) /0.045	0.406
Europe	12/165 (7%)	22/155 (14%)	0.4742 (0.2261, 0.9945) /0.048	-6.9208 (-13.6946, -0.1470) /0.045	0.5124 (0.2626, 0.9997) /0.050	
Rest of World	2/ 44 (5%)	8/ 37 (22%)	0.1726 (0.0342, 0.8724) /0.034	-17.0762 (-31.6990, -2.4534) /0.022	0.2102 (0.0475, 0.9296) /0.040	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	13/118 (11%)	14/135 (10%)				
Europe	13/165 (8%)	14/155 (9%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	4/118 (3%)	9/135 (7%)				
Europe	16/165 (10%)	24/155 (15%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	8/118 (7%)	8/135 (6%)				
Europe	15/165 (9%)	15/155 (10%)				
Rest of World	0/ 44	5/ 37 (14%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	13/118 (11%)	10/135 (7%)				
Europe	6/165 (4%)	8/155 (5%)				
Rest of World	4/ 44 (9%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	7/118 (6%)	16/135 (12%)	0.4690 (0.1860, 1.1829) /0.109	-5.9196 (-12.8402, 1.0009) /0.094	0.5005 (0.2133, 1.1748) /0.112	0.307
Europe	1/165 (<1%)	7/155 (5%)	0.1289 (0.0157, 1.0602) /0.057	-3.9101 (-7.3871, -0.4331) /0.028	0.1342 (0.0167, 1.0783) /0.059	
Rest of World	0/ 44	1/ 37 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9614 (-35.9319, 26.0091) /0.754	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
North America	7/118 (6%)	8/135 (6%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
North America	3/118 (3%)	0/135				
Europe	10/165 (6%)	7/155 (5%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
North America	4/118 (3%)	5/135 (4%)				
Europe	4/165 (2%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
North America	8/118 (7%)	6/135 (4%)				
Europe	4/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	1/118 (<1%)	4/135 (3%)				
Europe	3/165 (2%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
North America	6/118 (5%)	5/135 (4%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
North America	2/118 (2%)	2/135 (1%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site warmth						
North America	2/118 (2%)	5/135 (4%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
North America	3/118 (3%)	4/135 (3%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
North America	2/118 (2%)	1/135 (<1%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Discomfort						
North America	0/118	0/135				
Europe	4/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site reaction						
North America	3/118 (3%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	0/118	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
North America	3/118 (3%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site haematoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gait disturbance						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site papule						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic fatigue syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Induration						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Inflammation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discharge						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site fibrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site hypersensitivity						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site mass						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site necrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site rash						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mass						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sensation of foreign body						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sluggishness						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thirst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Xerosis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	60/118 (51%)	78/135 (58%)	0.7560 (0.4599, 1.2425) /0.270	-6.9303 (-19.2096, 5.3489) /0.269	0.8801 (0.7002, 1.1061) /0.273	0.943
Europe	92/165 (56%)	101/155 (65%)	0.6738 (0.4291, 1.0580) /0.086	-9.4037 (-20.0665, 1.2590) /0.084	0.8557 (0.7161, 1.0225) /0.086	
Rest of World	24/ 44 (55%)	22/ 37 (59%)	0.8182 (0.3377, 1.9820) /0.657	-4.9140 (-26.5179, 16.6899) /0.656	0.9174 (0.6281, 1.3399) /0.655	

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(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
North America	5/118 (4%)	7/135 (5%)				
Europe	39/165 (24%)	40/155 (26%)				
Rest of World	4/ 44 (9%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	21/118 (18%)	32/135 (24%)	0.6968 (0.3762, 1.2906) /0.251	-5.9071 (-15.8613, 4.0472) /0.245	0.7508 (0.4591, 1.2279) /0.253	0.827
Europe	7/165 (4%)	12/155 (8%)	0.5280 (0.2023, 1.3778) /0.192	-3.4995 (-8.7110, 1.7120) /0.188	0.5480 (0.2215, 1.3559) /0.193	
Rest of World	7/ 44 (16%)	9/ 37 (24%)	0.5886 (0.1953, 1.7735) /0.346	-8.4152 (-25.9627, 9.1322) /0.347	0.6540 (0.2697, 1.5859) /0.347	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
North America	4/118 (3%)	7/135 (5%)	0.6416 (0.1831, 2.2487) /0.488	-1.7954 (-6.7603, 3.1696) /0.478	0.6538 (0.1962, 2.1779) /0.489	0.550
Europe	7/165 (4%)	15/155 (10%)	0.4135 (0.1639, 1.0434) /0.061	-5.4350 (-11.0136, 0.1436) /0.056	0.4384 (0.1837, 1.0463) /0.063	
Rest of World	0/ 44	1/ 37 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9614 (-35.9319, 26.0091) /0.754	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis						
North America	3/118 (3%)	7/135 (5%)				
Europe	7/165 (4%)	9/155 (6%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Syphilis						
North America	3/118 (3%)	5/135 (4%)				
Europe	3/165 (2%)	9/155 (6%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
North America	4/118 (3%)	3/135 (2%)				
Europe	7/165 (4%)	7/155 (5%)				
Rest of World	0/ 44	1/ 37 (3%)				
Influenza						
North America	4/118 (3%)	2/135 (1%)				
Europe	4/165 (2%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	5/118 (4%)	6/135 (4%)				
Europe	4/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Sinusitis						
North America	2/118 (2%)	4/135 (3%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/118	0/135				
Europe	4/165 (2%)	8/155 (5%)				
Rest of World	2/ 44 (5%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydial infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	7/165 (4%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract infection						
North America	2/118 (2%)	4/135 (3%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	6/165 (4%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	3/118 (3%)	4/135 (3%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/118	0/135				
Europe	4/165 (2%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
North America	0/118	1/135 (<1%)				
Europe	4/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	4/118 (3%)	4/135 (3%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral herpes						
North America	0/118	1/135 (<1%)				
Europe	2/165 (1%)	6/155 (4%)				
Rest of World	0/ 44	0/ 37				
Rhinitis						
North America	1/118 (<1%)	0/135				
Europe	3/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
North America	3/118 (3%)	2/135 (1%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	1/118 (<1%)	5/135 (4%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Folliculitis						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis viral						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	1/118 (<1%)	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea versicolour						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	1/118 (<1%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hordeolum						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	4/ 44 (9%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/118	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	2/ 44 (5%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth abscess						
North America	0/118	2/135 (1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	0/118	4/135 (3%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingivitis						
North America	0/118	0/135				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
North America	0/118	0/135				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth infection						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acarodermatitis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Cellulitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diverticulitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis externa						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotons illitis						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Secondary syphilis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis chlamydial						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Helicobacter infection						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatitis E						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranuloma venereum						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Otitis media						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Postoperative wound infection						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Shigella infection						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin infection						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ureaplasma infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Anal abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod infestation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asymptomatic bacteriuria						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial diarrhoea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial rhinitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vaginosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis viral						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest wall abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic sinusitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis viral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cutaneous blastomycosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatophytosis of nail						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Device related infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea infectious						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection bacterial						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterobiasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterovirus infection						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epiglottitis obstructive						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema migrans						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
External ear cellulitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis viral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis Escherichia coli						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital candidiasis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival abscess						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infectious mononucleosiss						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Labyrinthitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lice infestation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oesophageal candidiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ophthalmic herpes zoster						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pericoronitiss						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Perirectal abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peritonitis abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis bacterial						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis mycoplasmal						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis mycoplasmal						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulmonary tuberculosis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Schistosomiasis cutaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sialoadenitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin bacterial infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis genital						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea capitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tinea cruris						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Tinea pedis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheobronchitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trichomoniasis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral rash						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral rhinitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	31/118 (26%)	43/135 (32%)	0.7624 (0.4412, 1.3174) /0.331	-5.5807 (-16.7531, 5.5918) /0.328	0.8248 (0.5583, 1.2184) /0.333	0.158
Europe	29/165 (18%)	44/155 (28%)	0.5379 (0.3161, 0.9154) /0.022	-10.8113 (-19.9825, -1.6402) /0.021	0.6191 (0.4091, 0.9370) /0.023	
Rest of World	11/ 44 (25%)	6/ 37 (16%)	1.7222 (0.5682, 5.2204) /0.337	8.7838 (-8.6736, 26.2411) /0.324	1.5417 (0.6309, 3.7673) /0.342	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	12/118 (10%)	9/135 (7%)				
Europe	10/165 (6%)	12/155 (8%)				
Rest of World	3/ 44 (7%)	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea North America	7/118 (6%)	13/135 (10%)	0.5918 (0.2279, 1.5366) /0.281	-3.6974 (-10.2495, 2.8546) /0.269	0.6160 (0.2542, 1.4927) /0.283	0.111
Europe	0/165	5/155 (3%)	<0.0001 (<0.0001, -) />0.999	-5.4674 (-21.3950, 10.4602) /0.501	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 44 (2%)	2/ 37 (5%)	0.4070 (0.0354, 4.6766) /0.470	-3.1327 (-11.6461, 5.3807) /0.471	0.4205 (0.0397, 4.4544) /0.472	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
North America	1/118 (<1%)	3/135 (2%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	0/118	4/135 (3%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	2/ 44 (5%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Toothache						
North America	2/118 (2%)	0/135				
Europe	2/165 (1%)	7/155 (5%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrooesophageal reflux disease						
North America	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	2/118 (2%)	2/135 (1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	3/118 (3%)	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
North America	1/118 (<1%)	3/135 (2%)				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
North America	3/118 (3%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anogenital dysplasia						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	1/ 44 (2%)	0/ 37				
Anal fistula						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flatulence						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry mouth						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Noninfective gingivitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal tenderness						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal pruritus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cheilitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Crohn's disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dental caries						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food poisoning						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastric disorder						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival hypertrophy						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glossitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Haematemesis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematochezi						
a						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoida 1 haemorrhage						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hiatus hernia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertrophic anal papilla						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intestinal polyp						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine polyp						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oesophagitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oroantral fistula						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Perianal erythema						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodontal disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Proctitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Tooth disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	26/118 (22%)	32/135 (24%)				
Europe	33/165 (20%)	40/155 (26%)				
Rest of World	6/ 44 (14%)	7/ 37 (19%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	4/118 (3%)	6/135 (4%)				
Europe	11/165 (7%)	13/155 (8%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Arthralgia						
North America	8/118 (7%)	7/135 (5%)				
Europe	5/165 (3%)	7/155 (5%)				
Rest of World	3/ 44 (7%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
North America	4/118 (3%)	8/135 (6%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
North America	6/118 (5%)	2/135 (1%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
North America	4/118 (3%)	3/135 (2%)				
Europe	4/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
North America	1/118 (<1%)	5/135 (4%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	2/118 (2%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neck pain						
North America	0/118	0/135				
Europe	3/165 (2%)	2/155 (1%)				
Rest of World	2/ 44 (5%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
North America	0/118	0/135				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
North America	0/118	0/135				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
North America	0/118	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
North America	0/118	1/135 (<1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Bursitis						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Exostosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint contracture						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb discomfort						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Arthropathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical spinal stenosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Costochondritis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Femoroacetabular impingement						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Groin pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint stiffness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal stiffness						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteochondritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosi s						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteopenia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Pain in jaw						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periarthriti s						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scoliosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendon disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigger finger						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	28/118 (24%)	30/135 (22%)				
Europe	20/165 (12%)	25/155 (16%)				
Rest of World	6/ 44 (14%)	9/ 37 (24%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus						
North America	5/118 (4%)	2/135 (1%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	2/ 44 (5%)	2/ 37 (5%)				
Rash						
North America	2/118 (2%)	5/135 (4%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	3/ 44 (7%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Eczema						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	3/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	2/ 37 (5%)				
Alopecia						
North America	3/118 (3%)	0/135				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
North America	1/118 (<1%)	3/135 (2%)				
Europe	4/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				
Dermatitis						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acne						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				
Dermal cyst						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosi s						
North America	0/118	3/135 (2%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	4/118 (3%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seborrhoeic dermatitis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Dry skin						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash erythematous						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin exfoliation						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin mass						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Androgenetic alopecia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chloasma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Cold sweat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug eruption						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ecchymosis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema asteatotic						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Granuloma annulare						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand dermatitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Keratosis pilaris						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lichen sclerosus						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macule						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Miliaria						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nail bed inflammation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain of skin						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Petechiae						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pigmentation disorder						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis rosea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Purpura						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash morbilliform						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin discolouration						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypertrophy						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin irritation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin swelling						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Solar dermatitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	24/118 (20%)	18/135 (13%)				
Europe	18/165 (11%)	29/155 (19%)				
Rest of World	3/ 44 (7%)	5/ 37 (14%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
North America	11/118 (9%)	8/135 (6%)				
Europe	10/165 (6%)	16/155 (10%)				
Rest of World	1/ 44 (2%)	3/ 37 (8%)				
Dizziness						
North America	8/118 (7%)	2/135 (1%)				
Europe	3/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paraesthesia						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Presyncope						
North America	1/118 (<1%)	3/135 (2%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Sciatica						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Somnolence						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Head discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia ^a						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Syncope						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Amnesia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burning sensation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Carpal tunnel syndrome						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral infarction						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical radiculopathy						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Disturbance in attention						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysarthria						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dysgeusia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperaesthesia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersomnia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hypertonia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neuropathy peripheral						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Polyneuropathy						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Radiculopathy						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	18/118 (15%)	26/135 (19%)				
Europe	15/165 (9%)	23/155 (15%)				
Rest of World	6/ 44 (14%)	6/ 37 (16%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
North America	6/118 (5%)	9/135 (7%)				
Europe	5/165 (3%)	8/155 (5%)				
Rest of World	4/ 44 (9%)	4/ 37 (11%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	2/118 (2%)	5/135 (4%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	2/118 (2%)	2/135 (1%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
North America	3/118 (3%)	6/135 (4%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	3/118 (3%)	3/135 (2%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Asthma						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Epistaxis						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Catarrh						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Haemoptysis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rales						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rhinorrhoea						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry throat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Interstitial lung disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal oedema						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal septum deviation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Painful respiration						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pleuritic pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	15/118 (13%)	31/135 (23%)	0.4886 (0.2490, 0.9586) /0.037	-10.2511 (-19.5495, -0.9527) /0.031	0.5536 (0.3147, 0.9738) /0.040	0.992
Europe	13/165 (8%)	22/155 (14%)	0.5170 (0.2507, 1.0666) /0.074	-6.3148 (-13.1764, 0.5469) /0.071	0.5551 (0.2899, 1.0629) /0.076	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rest of World	3/ 44 (7%)	5/ 37 (14%)	0.4683 (0.1041, 2.1075) /0.323	-6.6953 (-19.9923, 6.6017) /0.324	0.5045 (0.1291, 1.9716) /0.325	
Arthropod bite						
North America	0/118	4/135 (3%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
North America	4/118 (3%)	5/135 (4%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	5/118 (4%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Contusion						
North America	1/118 (<1%)	2/135 (1%)				
Europe	3/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin laceration						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	0/118	3/135 (2%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin abrasion						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rib fracture						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Animal bite						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Heat stroke						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Joint injury						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Meniscus injury						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wrist fracture						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bone contusion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burns second degree						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chemical burns of eye						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Concussion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Corneal abrasion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibula fracture						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Head injury						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury corneal						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lip injury						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nail injury						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Procedural pain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scapula fracture						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sunburn						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Thermal burn						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Traumatic haematoma						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ulna fracture						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	14/118 (12%)	24/135 (18%)				
Europe	17/165 (10%)	16/155 (10%)				
Rest of World	4/ 44 (9%)	4/ 37 (11%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
North America	3/118 (3%)	12/135 (9%)				
Europe	5/165 (3%)	6/155 (4%)				
Rest of World	3/ 44 (7%)	0/ 37				
Anxiety						
North America	5/118 (4%)	4/135 (3%)				
Europe	4/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression North America	2/118 (2%)	3/135 (2%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	0/118	4/135 (3%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	0/118	0/135				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Libido decreased						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Panic attack						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Irritability						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with mixed anxiety and depressed mood						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Agoraphobia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Emotional distress						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of libido						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mood swings						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nervousness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic stress disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Restlessness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Stress						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	9/118 (8%)	10/135 (7%)				
Europe	5/165 (3%)	16/155 (10%)				
Rest of World	4/ 44 (9%)	4/ 37 (11%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/118	2/135 (1%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
North America	2/118 (2%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin unconjugated increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
CD4 lymphocytes decreased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Campylobacter test positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydia test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Culture urine positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematocrit increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intraocular pressure increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Parasite stool test positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Shigella test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	3/118 (3%)	8/135 (6%)				
Europe	12/165 (7%)	7/155 (5%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	2/118 (2%)	3/135 (2%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatomegaly						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular cyst						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrophic vulvovaginitis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Balanoposthitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Breast pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital erythema						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematospermia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile burning sensation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile discharge						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Priapism						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular mass						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular torsion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testis discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine polyp						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	2/118 (2%)	3/135 (2%)				
Europe	7/165 (4%)	14/155 (9%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	6/155 (4%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin papilloma						
North America	0/118	0/135				
Europe	0/165	6/155 (4%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Basal cell carcinoma						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibroma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Kaposi's sarcoma						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma of breast						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral papilloma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	2/118 (2%)	5/135 (4%)				
Europe	10/165 (6%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	3/ 37 (8%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
North America	2/118 (2%)	3/135 (2%)				
Europe	7/165 (4%)	2/155 (1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Flushing						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematoma						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure inadequately controlled						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Hypotension						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral coldness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicose vein						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	3/118 (3%)	6/135 (4%)				
Europe	3/165 (2%)	8/155 (5%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Retinal detachment						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blepharospasm						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Chalazion						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diplopia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry eye						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Eyelid cyst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid oedema						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glaucoma						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Iritis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mydriasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ocular hyperaemia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ulcerative keratitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vision blurred						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous floaters						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	2/118 (2%)	4/135 (3%)	0.5647 (0.1015, 3.1397) /0.514	-1.2680 (-4.9566, 2.4205) /0.500	0.5720 (0.1067, 3.0672) /0.514	0.399
Europe	2/165 (1%)	10/155 (6%)	0.1779 (0.0383, 0.8254) /0.027	-5.2395 (-9.4521, -1.0269) /0.015	0.1879 (0.0418, 0.8439) /0.029	
Rest of World	2/ 44 (5%)	2/ 37 (5%)	0.8333 (0.1116, 6.2234) /0.859	-0.8600 (-10.3977, 8.6778) /0.860	0.8409 (0.1244, 5.6820) /0.859	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition urgency						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Nocturia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Pollakiuria						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Leukocyturia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureterolithiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	6/118 (5%)	7/135 (5%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Vertigo						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Deafness neurosensory						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tympanic membrane perforation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	5/118 (4%)	1/135 (<1%)				
Europe	6/165 (4%)	8/155 (5%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	4/118 (3%)	1/135 (<1%)				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypersensitivity						
North America	0/118	0/135				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	4/118 (3%)	9/135 (7%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Obesity						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cachexia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gluten sensitivity						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gout						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperglycaemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperlipasae mia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypokalaemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	1/118 (<1%)	3/135 (2%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Tachycardia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

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Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angina pectoris						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrial fibrillation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiac aneurysm						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	2/118 (2%)	1/135 (<1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymph node pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
North America	2/118 (2%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrial septal defect						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign familial pemphigus						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type V hyperlipidaemia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Goitre						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cholelithiasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatomegaly						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Jaundice						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17
 Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress at work						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD,

OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively),

using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models

with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.17

Analysis of Proportion of Subjects with Adverse Events by System Organ Class and Preferred Term
 (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR, p-value and interaction p-values are only provided for AEs with

(1) significant difference in occurrences between treatment arms on the study level (p<0.05)

(2) at least 1 level of the subgroup has number of events >=10 regardless of treatment group.

OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	34/ 84 (40%)	35/ 98 (36%)	1.2240 (0.6714, 2.2313) /0.509	4.7619 (-9.3865, 18.9103) /0.509	1.1333 (0.7819, 1.6428) /0.509	0.455
35 - <50	57/154 (37%)	60/143 (42%)	0.8129 (0.5100, 1.2956) /0.384	-4.9451 (-16.0615, 6.1714) /0.383	0.8821 (0.6653, 1.1697) /0.384	
>=50	34/ 89 (38%)	29/ 86 (34%)	1.2150 (0.6545, 2.2556) /0.537	4.4813 (-9.7219, 18.6845) /0.536	1.1329 (0.7617, 1.6850) /0.538	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	41/ 84 (49%)	41/ 98 (42%)	1.3256 (0.7373, 2.3833) /0.346	6.9728 (-7.5065, 21.4520) /0.345	1.1667 (0.8471, 1.6068) /0.345	0.832
35 - <50	78/154 (51%)	70/143 (49%)	1.0703 (0.6788, 1.6875) /0.770	1.6983 (-9.6806, 13.0772) /0.770	1.0347 (0.8231, 1.3006) /0.770	
>=50	46/ 89 (52%)	42/ 86 (49%)	1.1207 (0.6194, 2.0278) /0.706	2.8482 (-11.9638, 17.6601) /0.706	1.0583 (0.7878, 1.4217) /0.707	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	41/ 84 (49%)	40/ 98 (41%)	1.3826 (0.7682, 2.4882) /0.280	7.9932 (-6.4621, 22.4485) /0.278	1.1958 (0.8651, 1.6530) /0.279	0.562
35 - <50	71/154 (46%)	68/143 (48%)	0.9435 (0.5979, 1.4888) /0.803	-1.4486 (-12.8055, 9.9084) /0.803	0.9695 (0.7608, 1.2356) /0.803	
>=50	45/ 89 (51%)	39/ 86 (45%)	1.2325 (0.6805, 2.2325) /0.490	5.2130 (-9.5720, 19.9980) /0.490	1.1150 (0.8178, 1.5200) /0.491	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule <35	10/ 84 (12%)	13/ 98 (13%)	0.8836 (0.3660, 2.1331) /0.783	-1.3605 (-11.0074, 8.2863) /0.782	0.8974 (0.4150, 1.9405) /0.783	0.414
35 - <50	11/154 (7%)	21/143 (15%)	0.4469 (0.2072, 0.9637) /0.040	-7.5425 (-14.6277, -0.4572) /0.037	0.4864 (0.2432, 0.9727) /0.042	
>=50	6/ 89 (7%)	13/ 86 (15%)	0.4059 (0.1468, 1.1226) /0.082	-8.3747 (-17.5645, 0.8150) /0.074	0.4460 (0.1776, 1.1200) /0.086	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort <35	2/ 84 (2%)	3/ 98 (3%)	0.7724 (0.1260, 4.7356) /0.780	-0.6803 (-5.3985, 4.0379) /0.777	0.7778 (0.1331, 4.5448) /0.780	0.403
35 - <50	12/154 (8%)	10/143 (7%)	1.1239 (0.4700, 2.6878) /0.793	0.7992 (-5.1501, 6.7485) /0.792	1.1143 (0.4968, 2.4992) /0.793	
>=50	6/ 89 (7%)	12/ 86 (14%)	0.4458 (0.1593, 1.2472) /0.124	-7.2119 (-16.1990, 1.7752) /0.116	0.4831 (0.1898, 1.2296) /0.127	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration <35	5/ 84 (6%)	6/ 98 (6%)	0.9705 (0.2853, 3.3013) /0.962	-0.1701 (-7.1077, 6.7676) /0.962	0.9722 (0.3077, 3.0719) /0.962	0.157
35 - <50	11/154 (7%)	9/143 (6%)	1.1453 (0.4601, 2.8507) /0.771	0.8492 (-4.8419, 6.5402) /0.770	1.1349 (0.4846, 2.6580) /0.771	
>=50	3/ 89 (3%)	10/ 86 (12%)	0.2651 (0.0704, 0.9990) /0.050	-8.2571 (-16.0004, -0.5138) /0.037	0.2899 (0.0826, 1.0176) /0.053	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia <35	5/ 84 (6%)	7/ 98 (7%)	0.8228 (0.2512, 2.6953) /0.747	-1.1905 (-8.3738, 5.9928) /0.745	0.8333 (0.2746, 2.5287) /0.748	0.734
35 - <50	6/154 (4%)	12/143 (8%)	0.4426 (0.1615, 1.2124) /0.113	-4.4955 (-9.9719, 0.9809) /0.108	0.4643 (0.1790, 1.2043) /0.115	
>=50	4/ 89 (4%)	7/ 86 (8%)	0.5311 (0.1497, 1.8837) /0.327	-3.6452 (-10.8511, 3.5608) /0.321	0.5522 (0.1676, 1.8190) /0.329	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling <35	3/ 84 (4%)	2/ 98 (2%)	1.7778 (0.2899, 10.9007) /0.534	1.5306 (-3.3259, 6.3871) /0.537	1.7500 (0.2995, 10.2258) /0.534	0.313
35 - <50	5/154 (3%)	8/143 (6%)	0.5663 (0.1809, 1.7730) /0.329	-2.3477 (-7.0406, 2.3453) /0.327	0.5804 (0.1944, 1.7329) /0.330	
>=50	6/ 89 (7%)	3/ 86 (3%)	2.0000 (0.4840, 8.2652) /0.338	3.2532 (-3.2410, 9.7474) /0.326	1.9326 (0.4991, 7.4835) /0.340	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue <35	2/ 84 (2%)	7/ 98 (7%)	0.3171 (0.0640, 1.5698) /0.159	-4.7619 (-10.8140, 1.2902) /0.123	0.3333 (0.0712, 1.5614) /0.163	0.958
35 - <50	3/154 (2%)	8/143 (6%)	0.3353 (0.0872, 1.2895) /0.112	-3.6464 (-7.9998, 0.7071) /0.101	0.3482 (0.0942, 1.2870) /0.114	
>=50	1/ 89 (1%)	4/ 86 (5%)	0.2330 (0.0255, 2.1275) /0.197	-3.5276 (-8.4879, 1.4328) /0.163	0.2416 (0.0275, 2.1182) /0.200	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus <35	2/ 84 (2%)	2/ 98 (2%)	1.1707 (0.1613, 8.4963) /0.876	0.3401 (-3.9570, 4.6373) /0.877	1.1667 (0.1680, 8.1038) /0.876	0.431
35 - <50	3/154 (2%)	8/143 (6%)	0.3353 (0.0872, 1.2895) /0.112	-3.6464 (-7.9998, 0.7071) /0.101	0.3482 (0.0942, 1.2870) /0.114	
>=50	1/ 89 (1%)	5/ 86 (6%)	0.1841 (0.0211, 1.6093) /0.126	-4.6904 (-10.0992, 0.7184) /0.089	0.1933 (0.0230, 1.6205) /0.130	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema <35	2/ 84 (2%)	1/ 98 (1%)	2.3659 (0.2107, 26.5634) /0.485	1.3605 (-2.4589, 5.1800) /0.485	2.3333 (0.2154, 25.2796) /0.486	0.581
35 - <50	6/154 (4%)	8/143 (6%)	0.6841 (0.2314, 2.0224) /0.492	-1.6983 (-6.5488, 3.1522) /0.493	0.6964 (0.2477, 1.9581) /0.493	
>=50	1/ 89 (1%)	2/ 86 (2%)	0.4773 (0.0425, 5.3620) /0.549	-1.2020 (-5.0674, 2.6634) /0.542	0.4831 (0.0446, 5.2313) /0.549	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	6/154 (4%)	3/143 (2%)				
>=50	4/ 89 (4%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills <35	0/ 84	0/ 98	NC	NC	NC	0.638
35 - <50	5/154 (3%)	5/143 (3%)	0.9262 (0.2624, 3.2685) /0.905	-0.2498 (-4.3607, 3.8612) /0.905	0.9286 (0.2746, 3.1406) /0.905	
>=50	5/ 89 (6%)	2/ 86 (2%)	2.5000 (0.4718, 13.2470) /0.281	3.2924 (-2.4550, 9.0398) /0.262	2.4157 (0.4815, 12.1196) /0.284	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	0/ 89	5/ 86 (6%)				
Injection site bruising						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	5/154 (3%)	2/143 (1%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Malaise						
<35	0/ 84	2/ 98 (2%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Pain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				
Discomfort						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				
Injection site anaesthesia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chest pain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Nodule						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site papule						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Vessel puncture site haematoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Chronic fatigue syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gait disturbance						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Induration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inflammation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site mass						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Injection site rash						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mass						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Non-cardiac chest pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Peripheral swelling						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Sluggishness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temperature regulation disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Thirst						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Xerosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	26/ 84 (31%)	33/ 98 (34%)	0.8830 (0.4730, 1.6481) /0.696	-2.7211 (-16.3330, 10.8909) /0.695	0.9192 (0.6019, 1.4037) /0.696	0.917
35 - <50	53/154 (34%)	56/143 (39%)	0.8152 (0.5082, 1.3077) /0.397	-4.7453 (-15.7136, 6.2231) /0.396	0.8788 (0.6518, 1.1848) /0.397	
>=50	26/ 89 (29%)	31/ 86 (36%)	0.7322 (0.3882, 1.3809) /0.336	-6.8330 (-20.6977, 7.0317) /0.334	0.8104 (0.5279, 1.2443) /0.337	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<35	7/ 84 (8%)	9/ 98 (9%)	0.8990 (0.3197, 2.5276) /0.840	-0.8503 (-9.0739, 7.3732) /0.839	0.9074 (0.3531, 2.3317) /0.840	0.882
35 - <50	18/154 (12%)	22/143 (15%)	0.7279 (0.3727, 1.4216) /0.352	-3.6963 (-11.4885, 4.0959) /0.353	0.7597 (0.4254, 1.3567) /0.353	
>=50	10/ 89 (11%)	10/ 86 (12%)	0.9620 (0.3790, 2.4416) /0.935	-0.3920 (-9.8232, 9.0393) /0.935	0.9663 (0.4235, 2.2047) /0.935	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection <35	3/ 84 (4%)	10/ 98 (10%)	0.3259 (0.0866, 1.2262) /0.097	-6.6327 (-13.8206, 0.5553) /0.071	0.3500 (0.0996, 1.2300) /0.102	0.466
35 - <50	14/154 (9%)	16/143 (11%)	0.7938 (0.3725, 1.6912) /0.550	-2.0979 (-8.9761, 4.7803) /0.550	0.8125 (0.4115, 1.6041) /0.550	
>=50	7/ 89 (8%)	12/ 86 (14%)	0.5264 (0.1968, 1.4078) /0.201	-6.0883 (-15.3029, 3.1263) /0.195	0.5637 (0.2329, 1.3641) /0.204	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	3/ 84 (4%)	8/ 98 (8%)	0.4167 (0.1069, 1.6241) /0.207	-4.5918 (-11.3102, 2.1265) /0.180	0.4375 (0.1199, 1.5965) /0.211	NC
35 - <50	6/154 (4%)	6/143 (4%)	0.9257 (0.2916, 2.9387) /0.896	-0.2997 (-4.7873, 4.1879) /0.896	0.9286 (0.3065, 2.8133) /0.896	
>=50	0/ 89	0/ 86	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Pharyngitis						
<35	2/ 84 (2%)	5/ 98 (5%)				
35 - <50	4/154 (3%)	3/143 (2%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Syphilis						
<35	2/ 84 (2%)	7/ 98 (7%)				
35 - <50	2/154 (1%)	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis <35	0/ 84	1/ 98 (1%)				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	3/ 89 (3%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea <35	8/ 84 (10%)	3/ 98 (3%)	3.3333 (0.8549, 12.9971) /0.083	6.4626 (-0.6815, 13.6067) /0.076	3.1111 (0.8525, 11.3529) /0.086	NC
35 - <50	0/154	3/143 (2%)	<0.0001 (<0.0001, -) />0.999	-4.3714 (-20.8560, 12.1131) /0.603	<0.0001 (<0.0001, -) />0.999	
>=50	0/ 89	0/ 86	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza						
<35	2/ 84 (2%)	0/ 98				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Sinusitis						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
<35	4/ 84 (5%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Respiratory tract infection						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				
Rhinitis						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Urinary tract infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral herpes						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				
Urethritis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral infection						
<35	3/ 84 (4%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Viral upper respiratory tract infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Folliculitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				
Tonsillitis						
<35	0/ 84	4/ 98 (4%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Herpes simplex						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Hordeolum						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Ear infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fungal skin infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Gastroenteritis viral						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingivitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Herpes zoster						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Onychomycosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				
Proctitis gonococcal						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Furuncle						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Otitis externa						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Tooth abscess						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Vaginal infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Body tinea						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lymphogranuloma venereum						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Mycoplasma genitalium infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Oropharyngeal gonococcal infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Paronychia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Postoperative wound infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin infection						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Staphylococcal infection						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Viral pharyngitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Arthropod infestation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bronchitis viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Candida infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cellulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Chronic sinusitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis viral						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cutaneous blastomycosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cystitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enteritis infectious						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Enterovirus infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erythema migrans						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Escherichia urinary tract infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

External ear cellulitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Gastritis viral						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Genital herpes simplex						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Groin abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis E						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Infectious mononucleosis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Labyrinthitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Mycoplasma infection <35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis media acute						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Penile infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pericoronitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Peritonsillar abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngeal chlamydia infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pharyngitis bacterial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Pharyngitis streptococcal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngotonsillitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Primary syphilis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pulpitis dental						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Schistosomiasis cutaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Syphilis genital						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea capitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tinea cruris						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea pedis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tracheitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheobronchitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Trichomoniasis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Varicella						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rash						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Viral rhinitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	15/ 84 (18%)	17/ 98 (17%)	1.0358 (0.4820, 2.2259) /0.928	0.5102 (-10.5931, 11.6135) /0.928	1.0294 (0.5482, 1.9332) /0.928	0.551
35 - <50	22/154 (14%)	31/143 (22%)	0.6022 (0.3299, 1.0990) /0.098	-7.3926 (-16.1193, 1.3341) /0.097	0.6590 (0.4010, 1.0829) /0.100	
>=50	15/ 89 (17%)	18/ 86 (21%)	0.7658 (0.3580, 1.6378) /0.491	-4.0763 (-15.6698, 7.5172) /0.491	0.8052 (0.4341, 1.4936) /0.492	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea <35	6/ 84 (7%)	3/ 98 (3%)	2.4359 (0.5900, 10.0564) /0.218	4.0816 (-2.3964, 10.5596) /0.217	2.3333 (0.6019, 9.0450) /0.220	0.362
35 - <50	10/154 (6%)	9/143 (6%)	1.0340 (0.4076, 2.6226) /0.944	0.1998 (-5.3670, 5.7666) /0.944	1.0317 (0.4317, 2.4659) /0.944	
>=50	4/ 89 (4%)	6/ 86 (7%)	0.6275 (0.1707, 2.3057) /0.483	-2.4824 (-9.3756, 4.4109) /0.480	0.6442 (0.1883, 2.2038) /0.483	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea <35	3/ 84 (4%)	6/ 98 (6%)	0.5679 (0.1376, 2.3441) /0.434	-2.5510 (-8.7380, 3.6360) /0.419	0.5833 (0.1505, 2.2613) /0.436	0.305
35 - <50	1/154 (<1%)	9/143 (6%)	0.0973 (0.0122, 0.7781) /0.028	-5.6444 (-9.8219, -1.4668) /0.008	0.1032 (0.0132, 0.8042) /0.030	
>=50	1/ 89 (1%)	2/ 86 (2%)	0.4773 (0.0425, 5.3620) /0.549	-1.2020 (-5.0674, 2.6634) /0.542	0.4831 (0.0446, 5.2313) /0.549	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	4/143 (3%)				
>=50	2/ 89 (2%)	3/ 86 (3%)				
Abdominal pain						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids						
<35	0/ 84	5/ 98 (5%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Constipation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	4/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				
Toothache						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vomiting						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Abdominal pain upper						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
<35	2/ 84 (2%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Abdominal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain lower						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Anogenital dysplasia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Flatulence						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Gastritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry mouth						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Gingival pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				
Irritable bowel syndrome						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective gingivitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Rectal discharge						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rectal haemorrhage						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Abdominal hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal tenderness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Anal fistula						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Angular cheilitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cheilitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Dental caries						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Food poisoning						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastric disorder						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gastrointestinal disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival hypertrophy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Haematemesis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematochezia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hiatus hernia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertrophic anal papilla						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hypoaesthesia oral						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Large intestine polyp						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Mouth ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophagitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pancreatitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Perianal erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Proctalgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
<35	5/ 84 (6%)	13/ 98 (13%)	0.4138 (0.1411, 1.2136) /0.108	-7.3129 (-15.7213, 1.0955) /0.088	0.4487 (0.1668, 1.2068) /0.112	0.270
35 - <50	18/154 (12%)	24/143 (17%)	0.6563 (0.3396, 1.2682) /0.210	-5.0949 (-13.0489, 2.8591) /0.209	0.6964 (0.3950, 1.2280) /0.211	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	18/ 89 (20%)	16/ 86 (19%)	1.1092 (0.5239, 2.3481) /0.787	1.6201 (-10.0967, 13.3368) /0.786	1.0871 (0.5938, 1.9901) /0.787	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain <35	1/ 84 (1%)	5/ 98 (5%)	0.2241 (0.0257, 1.9575) /0.176	-3.9116 (-8.8470, 1.0239) /0.120	0.2333 (0.0278, 1.9579) /0.180	0.262
35 - <50	7/154 (5%)	9/143 (6%)	0.7090 (0.2569, 1.9566) /0.507	-1.7483 (-6.9122, 3.4157) /0.507	0.7222 (0.2762, 1.8884) /0.507	
>=50	5/ 89 (6%)	3/ 86 (3%)	1.6468 (0.3813, 7.1135) /0.504	2.1296 (-4.0287, 8.2879) /0.498	1.6105 (0.3970, 6.5330) /0.505	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia <35	0/ 84	2/ 98 (2%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	0.278
35 - <50	3/154 (2%)	2/143 (1%)	1.4007 (0.2306, 8.5062) /0.714	0.5495 (-2.3607, 3.4596) /0.711	1.3929 (0.2361, 8.2154) /0.714	
>=50	7/ 89 (8%)	7/ 86 (8%)	0.9634 (0.3232, 2.8719) /0.947	-0.2744 (-8.3165, 7.7678) /0.947	0.9663 (0.3538, 2.6394) /0.947	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	5/143 (3%)				
>=50	1/ 89 (1%)	4/ 86 (5%)				
Myalgia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	2/143 (1%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				
Muscle contracture						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	3/ 86 (3%)				
Musculoskeletal chest pain <35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neck pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Tendonitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bursitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Intervertebra l disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Arthritis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Cervical spinal stenosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exostosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Femoroacetabular impingement						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Joint range of motion decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint stiffness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Joint swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Limb discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Muscle tightness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Musculoskeletal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal stiffness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Osteochondritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteopenia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Scoliosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Spinal osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Synovitis <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Temporomandibular joint syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tendon disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tenosynovitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Trigger finger						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	10/ 84 (12%)	13/ 98 (13%)	0.8836 (0.3660, 2.1331) /0.783	-1.3605 (-11.0074, 8.2863) /0.782	0.8974 (0.4150, 1.9405) /0.783	0.879
35 - <50	16/154 (10%)	21/143 (15%)	0.6736 (0.3363, 1.3490) /0.265	-4.2957 (-11.8376, 3.2462) /0.264	0.7075 (0.3847, 1.3011) /0.266	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	13/ 89 (15%)	15/ 86 (17%)	0.8096 (0.3601, 1.8202) /0.609	-2.8351 (-13.7052, 8.0349) /0.609	0.8375 (0.4238, 1.6547) /0.610	
Pruritus						
<35	3/ 84 (4%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	4/ 89 (4%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				
Eczema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	2/ 89 (2%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alopecia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	4/ 89 (4%)	0/ 86				
Acne						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Dermatitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seborrhoeic dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				
Night sweats						
<35	1/ 84 (1%)	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermal cyst						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Dermatitis contact						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry skin						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Hyperhidrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash erythematous						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Skin exfoliation						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin mass						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Urticaria						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Androgenetic alopecia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chloasma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cold sweat						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dermatitis atopic						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Drug eruption						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Ecchymosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema asteatotic						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intertrigo						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Keratosis pilaris						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macule						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Miliaria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail bed inflammation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Penile ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Petechiae						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pigmentation disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pityriasis rosea <35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Psoriasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Purpura						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rash morbilliform						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin discolouration						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin fissures						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypertrophy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Skin irritation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Solar dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	11/ 84 (13%)	10/ 98 (10%)	1.3260 (0.5333, 3.2971) /0.544	2.8912 (-6.4876, 12.2699) /0.546	1.2833 (0.5736, 2.8712) /0.544	0.254
35 - <50	8/154 (5%)	15/143 (10%)	0.4676 (0.1920, 1.1389) /0.094	-5.2947 (-11.4191, 0.8296) /0.090	0.4952 (0.2165, 1.1327) /0.096	
>=50	13/ 89 (15%)	14/ 86 (16%)	0.8797 (0.3871, 1.9990) /0.760	-1.6723 (-12.3829, 9.0382) /0.760	0.8973 (0.4481, 1.7966) /0.760	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough <35	4/ 84 (5%)	3/ 98 (3%)	1.5833 (0.3442, 7.2844) /0.555	1.7007 (-3.9890, 7.3903) /0.558	1.5555 (0.3583, 6.7540) /0.555	0.148
35 - <50	3/154 (2%)	10/143 (7%)	0.2642 (0.0712, 0.9804) /0.047	-5.0450 (-9.7605, -0.3294) /0.036	0.2786 (0.0782, 0.9919) /0.049	
>=50	6/ 89 (7%)	6/ 86 (7%)	0.9639 (0.2984, 3.1133) /0.951	-0.2352 (-7.7269, 7.2566) /0.951	0.9663 (0.3242, 2.8800) /0.951	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	4/ 89 (4%)	2/ 86 (2%)				
Sinus congestion						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Rhinitis allergic						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epistaxis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Asthma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Catarrh						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dyspnoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Productive cough						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rales						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Rhinorrhoea						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Bronchospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry throat						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Haemoptysis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Interstitial lung disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Nasal oedema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Painful respiration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pleuritic pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Respiratory disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	8/ 84 (10%)	9/ 98 (9%)	1.0409 (0.3828, 2.8306) /0.937	0.3401 (-8.1510, 8.8312) /0.937	1.0370 (0.4188, 2.5678) /0.937	0.604
35 - <50	20/154 (13%)	16/143 (11%)	1.1847 (0.5879, 2.3875) /0.635	1.7982 (-5.6100, 9.2065) /0.634	1.1607 (0.6264, 2.1506) /0.636	
>=50	6/ 89 (7%)	9/ 86 (10%)	0.6185 (0.2103, 1.8185) /0.383	-3.7235 (-12.0296, 4.5825) /0.380	0.6442 (0.2395, 1.7329) /0.384	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache <35	2/ 84 (2%)	2/ 98 (2%)	1.1707 (0.1613, 8.4963) /0.876	0.3401 (-3.9570, 4.6373) /0.877	1.1667 (0.1680, 8.1038) /0.876	0.876
35 - <50	13/154 (8%)	11/143 (8%)	1.1064 (0.4789, 2.5559) /0.813	0.7493 (-5.4438, 6.9423) /0.813	1.0974 (0.5081, 2.3702) /0.813	
>=50	3/ 89 (3%)	4/ 86 (5%)	0.7151 (0.1553, 3.2933) /0.667	-1.2804 (-7.1000, 4.5393) /0.666	0.7247 (0.1671, 3.1435) /0.667	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dizziness						
<35	5/ 84 (6%)	4/ 98 (4%)				
35 - <50	4/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Paraesthesia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Presyncope						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Somnolence						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lethargy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Amnesia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Burning sensation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cervical radiculopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysarthria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Dysgeusia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Head discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hyperaesthesia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersomnia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hypoaesthesia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Periodic limb movement disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyneuropathy						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Sciatica						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
<35	5/ 84 (6%)	10/ 98 (10%)	0.5570 (0.1825, 1.6996) /0.304	-4.2517 (-12.0950, 3.5916) /0.288	0.5833 (0.2076, 1.6392) /0.307	0.639
35 - <50	13/154 (8%)	17/143 (12%)	0.6834 (0.3192, 1.4627) /0.327	-3.4466 (-10.3327, 3.4396) /0.327	0.7101 (0.3578, 1.4091) /0.327	
>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia <35	2/ 84 (2%)	4/ 98 (4%)	0.5732 (0.1023, 3.2106) /0.527	-1.7007 (-6.7973, 3.3959) /0.513	0.5833 (0.1096, 3.1055) /0.528	0.323
35 - <50	4/154 (3%)	9/143 (6%)	0.3970 (0.1195, 1.3190) /0.132	-3.6963 (-8.4031, 1.0105) /0.124	0.4127 (0.1299, 1.3107) /0.133	
>=50	0/ 89	3/ 86 (3%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Abnormal dreams						
<35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depressed mood						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Libido decreased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nightmare						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Sleep disorder						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Drug abuse <35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritability						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Panic attack						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Adjustment disorder with depressed mood						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with mixed anxiety and depressed mood						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Agoraphobia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Emotional distress						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Loss of libido						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Major depression						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Mood swings						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervousness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Post-traumatic stress disorder						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
<35	4/ 84 (5%)	9/ 98 (9%)	0.4944 (0.1466, 1.6679) /0.256	-4.4218 (-11.7315, 2.8880) /0.236	0.5185 (0.1656, 1.6232) /0.259	0.322
35 - <50	5/154 (3%)	17/143 (12%)	0.2487 (0.0892, 0.6932) /0.008	-8.6414 (-14.6393, -2.6435) /0.005	0.2731 (0.1034, 0.7210) /0.009	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	7/ 89 (8%)	9/ 86 (10%)	0.7304 (0.2593, 2.0571) /0.552	-2.5999 (-11.1517, 5.9518) /0.551	0.7516 (0.2929, 1.9283) /0.552	
Arthropod bite						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	4/143 (3%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	0/ 86				
Contusion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Exposure to communicable disease						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain <35	0/ 84	0/ 98				
35 - <50	0/154	3/143 (2%)				
>=50	0/ 89	1/ 86 (1%)				
Skin laceration <35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Skin abrasion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Bone contusion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Concussion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Epicondylitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fall						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Foot fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Injection related reaction						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury corneal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lip injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Nail injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Road traffic accident						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sunburn						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Thermal burn						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Traumatic haematoma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ulna fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 84 (2%)	5/ 98 (5%)	0.4537 (0.0857, 2.4015) /0.353	-2.7211 (-8.1624, 2.7202) /0.327	0.4667 (0.0929, 2.3433) /0.355	0.580
35 - <50	7/154 (5%)	11/143 (8%)	0.5714 (0.2153, 1.5170) /0.261	-3.1469 (-8.6147, 2.3210) /0.259	0.5909 (0.2355, 1.4826) /0.262	
>=50	5/ 89 (6%)	4/ 86 (5%)	1.2202 (0.3165, 4.7048) /0.773	0.9668 (-5.5674, 7.5010) /0.772	1.2079 (0.3355, 4.3484) /0.773	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	0/ 89	1/ 86 (1%)				
Blood pressure increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Weight increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Blood glucose increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Low density lipoprotein increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Weight decreased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Aspartate aminotransferase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Blood bilirubin increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin unconjugated increased <35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Blood triglycerides increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydia test positive						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Escherichia test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Haemoglobin increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intraocular pressure increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Vitamin D decreased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	3/ 84 (4%)	5/ 98 (5%)				
35 - <50	2/154 (1%)	6/143 (4%)				
>=50	3/ 89 (3%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	0/154	3/143 (2%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Skin papilloma						
<35	0/ 84	3/ 98 (3%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acrochordon						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Basal cell carcinoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibroma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Fibrous histiocyctoma						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Lipoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma of breast						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urethral papilloma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	3/ 84 (4%)	3/ 98 (3%)	1.1728 (0.2304, 5.9712) /0.848	0.5102 (-4.7225, 5.7430) /0.848	1.1667 (0.2419, 5.6277) /0.848	0.977
35 - <50	2/154 (1%)	2/143 (1%)	0.9276 (0.1289, 6.6738) /0.941	-0.0999 (-2.7271, 2.5273) /0.941	0.9286 (0.1325, 6.5052) /0.941	
>=50	6/ 89 (7%)	6/ 86 (7%)	0.9639 (0.2984, 3.1133) /0.951	-0.2352 (-7.7269, 7.2566) /0.951	0.9663 (0.3242, 2.8800) /0.951	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertension						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	4/ 89 (4%)	2/ 86 (2%)				
Flushing						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematoma						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Peripheral venous disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hot flush						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hypotension						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Peripheral coldness						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Varicose vein						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	3/ 84 (4%)	6/ 98 (6%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	4/ 89 (4%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
<35	0/ 84	3/ 98 (3%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Prostatomegaly						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Balanoposthitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Breast pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital erythema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Menorrhagia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Testicular cyst						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular mass						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Testicular pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testis discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Uterine polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	5/ 89 (6%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Vertigo						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerumen impaction						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	2/ 89 (2%)	0/ 86				
Ear discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Excessive cerumen production						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Deafness neurosensory						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Eustachian tube dysfunction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<35	0/ 84	4/ 98 (4%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	1/ 89 (1%)	3/ 86 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysuria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	2/ 86 (2%)				
Micturition urgency						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nocturia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Haematuria						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Micturition disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Nephrolithiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephropathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pollakiuria						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Urinary tract disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	4/143 (3%)				
>=50	0/ 89	5/ 86 (6%)				
Blepharitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Dry eye						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Eyelid cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glaucoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Iritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mydriasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ocular hyperaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Vision blurred						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous floaters						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	3/ 89 (3%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Decreased appetite						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D deficiency						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Gluten sensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gout						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Hyperglycaemia ^a						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Hypokalaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Obesity						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Type 2 diabetes mellitus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	0/143				
>=50	2/ 89 (2%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Iron deficiency anaemia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymph node pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Lymphadenopathy						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Hypogonadism						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Goitre <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Palpitations						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tachycardia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hepatomegaly						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Menopause						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress at work						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type V hyperlipidaemia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	42/ 84 (50%)	51/ 98 (52%)	0.9216 (0.5144, 1.6510) /0.784	-2.0408 (-16.6066, 12.5250) /0.784	0.9608 (0.7217, 1.2790) /0.784	0.582
35 - <50	73/154 (47%)	59/143 (41%)	1.2831 (0.8106, 2.0310) /0.287	6.1439 (-5.1388, 17.4265) /0.286	1.1489 (0.8887, 1.4852) /0.289	
>=50	41/ 89 (46%)	41/ 86 (48%)	0.9375 (0.5176, 1.6979) /0.831	-1.6070 (-16.3944, 13.1804) /0.831	0.9663 (0.7048, 1.3248) /0.831	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	37/ 84 (44%)	38/ 98 (39%)	1.2430 (0.6875, 2.2472) /0.472	5.2721 (-9.0725, 19.6167) /0.471	1.1360 (0.8034, 1.6062) /0.471	0.722
35 - <50	48/154 (31%)	42/143 (29%)	1.0889 (0.6633, 1.7878) /0.736	1.7982 (-8.6537, 12.2501) /0.736	1.0612 (0.7509, 1.4999) /0.736	
>=50	22/ 89 (25%)	24/ 86 (28%)	0.8483 (0.4324, 1.6640) /0.632	-3.1879 (-16.2335, 9.8577) /0.632	0.8858 (0.5390, 1.4558) /0.632	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	34/ 84 (40%)	35/ 98 (36%)	1.2240 (0.6714, 2.2313) /0.509	4.7619 (-9.3865, 18.9103) /0.509	1.1333 (0.7819, 1.6428) /0.509	0.877
35 - <50	45/154 (29%)	37/143 (26%)	1.1827 (0.7098, 1.9707) /0.519	3.3467 (-6.8078, 13.5011) /0.518	1.1293 (0.7796, 1.6361) /0.520	
>=50	20/ 89 (22%)	20/ 86 (23%)	0.9565 (0.4723, 1.9372) /0.902	-0.7839 (-13.2306, 11.6627) /0.902	0.9663 (0.5607, 1.6654) /0.902	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	8/143 (6%)				
>=50	0/ 89	5/ 86 (6%)				
Injection site discomfort						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site induration						
<35	1/ 84 (1%)	0/ 98				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Pyrexia						
<35	3/ 84 (4%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	4/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
<35	5/ 84 (6%)	1/ 98 (1%)				
35 - <50	3/154 (2%)	3/143 (2%)				
>=50	0/ 89	2/ 86 (2%)				
Fatigue						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pruritus						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site erythema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Chills						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza like illness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Injection site bruising						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Malaise						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pain						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Discomfort						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	2/ 86 (2%)				
Injection site reaction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Feeling hot						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Vessel puncture site haematoma						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Gait disturbance						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Peripheral swelling						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discharge						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site fibrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site necrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	25/ 84 (30%)	30/ 98 (31%)	0.9605 (0.5089, 1.8125) /0.901	-0.8503 (-14.2242, 12.5235) /0.901	0.9722 (0.6239, 1.5150) /0.901	0.853
35 - <50	27/154 (18%)	31/143 (22%)	0.7681 (0.4322, 1.3651) /0.369	-4.1459 (-13.1834, 4.8917) /0.369	0.8088 (0.5090, 1.2850) /0.369	
>=50	14/ 89 (16%)	15/ 86 (17%)	0.8836 (0.3980, 1.9612) /0.761	-1.7115 (-12.7359, 9.3128) /0.761	0.9019 (0.4637, 1.7543) /0.761	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasopharyngitis						
<35	5/ 84 (6%)	6/ 98 (6%)	0.9705 (0.2853, 3.3013) /0.962	-0.1701 (-7.1077, 6.7676) /0.962	0.9722 (0.3077, 3.0719) /0.962	0.346
35 - <50	4/154 (3%)	1/143 (<1%)	3.7867 (0.4182, 34.2873) /0.236	1.8981 (-0.9613, 4.7575) /0.193	3.7143 (0.4201, 32.8397) /0.238	
>=50	4/ 89 (4%)	1/ 86 (1%)	4.0000 (0.4380, 36.5298) /0.219	3.3316 (-1.5326, 8.1958) /0.179	3.8652 (0.4408, 33.8920) /0.222	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection <35	5/ 84 (6%)	6/ 98 (6%)	0.9705 (0.2853, 3.3013) /0.962	-0.1701 (-7.1077, 6.7676) /0.962	0.9722 (0.3077, 3.0719) /0.962	0.855
35 - <50	4/154 (3%)	6/143 (4%)	0.6089 (0.1683, 2.2035) /0.450	-1.5984 (-5.7347, 2.5379) /0.449	0.6190 (0.1783, 2.1489) /0.450	
>=50	2/ 89 (2%)	3/ 86 (3%)	0.6360 (0.1036, 3.9031) /0.625	-1.2412 (-6.1929, 3.7106) /0.623	0.6442 (0.1103, 3.7611) /0.625	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	6/143 (4%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Pharyngitis						
<35	3/ 84 (4%)	3/ 98 (3%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Syphilis						
<35	1/ 84 (1%)	3/ 98 (3%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Bronchitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gonorrhoea						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Influenza						
<35	0/ 84	2/ 98 (2%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinusitis						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Chlamydial infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection viral						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	0/ 86				
Conjunctivitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Oral herpes						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Viral infection						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Folliculitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
<35	0/ 84	3/ 98 (3%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Tinea versicolour						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Fungal skin infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Herpes zoster						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
<35	2/ 84 (2%)	5/ 98 (5%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Furuncle						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Tooth abscess						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
<35	0/ 84	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Anal chlamydia infection						
<35	2/ 84 (2%)	4/ 98 (4%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Mycoplasma genitalium infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Oropharyngeal gonococcal infection						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Paronychia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Acarodermatitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cellulitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cystitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Enteritis infectious						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia urinary tract infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Genital herpes						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Pharyngeal chlamydia infection <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pharyngotonsillitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Primary syphilis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pulpitis dental						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Tracheitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Varicella						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis chlamydial						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Orchitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella infection						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Asymptomatic bacteriuria <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial diarrhoea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Bacterial rhinitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial vaginosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chest wall abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatophytosis of nail						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Device related infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea infectious						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Ear infection bacterial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterobiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Epididymitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia infection						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Gastroenteritis Escherichia coli						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Genitourinary tract infection						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lice infestation						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oesophageal candidiasis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Ophthalmic herpes zoster						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Perirectal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Proctitis chlamydial						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulmonary tuberculosis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Sialoadenitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin bacterial infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Subcutaneous abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	6/ 84 (7%)	7/ 98 (7%)	1.0000 (0.3225, 3.1006) />0.999	<0.0001 (-7.5054, 7.5054) />0.999	1.0000 (0.3497, 2.8598) />0.999	0.650
35 - <50	7/154 (5%)	12/143 (8%)	0.5198 (0.1988, 1.3596) /0.182	-3.8462 (-9.4563, 1.7640) /0.179	0.5417 (0.2194, 1.3375) /0.184	
>=50	4/ 89 (4%)	7/ 86 (8%)	0.5311 (0.1497, 1.8837) /0.327	-3.6452 (-10.8511, 3.5608) /0.321	0.5522 (0.1676, 1.8190) /0.329	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diarrhoea						
<35	3/ 84 (4%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Nausea						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	2/ 89 (2%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Abdominal pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Constipation						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal distension						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Toothache						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Abdominal pain upper						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Abdominal discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Gastritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Anal fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Colitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anal fissure						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Crohn's disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Gingival ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glossitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Haemorrhoids thrombosed						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intestinal polyp						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Periodontal disease						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Tongue ulceration						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	6/ 84 (7%)	6/ 98 (6%)	1.1795 (0.3657, 3.8045) /0.782	1.0204 (-6.2502, 8.2910) /0.783	1.1667 (0.3909, 3.4819) /0.782	0.155
35 - <50	11/154 (7%)	8/143 (6%)	1.2981 (0.5068, 3.3250) /0.587	1.5485 (-3.9952, 7.0921) /0.584	1.2768 (0.5286, 3.0838) /0.587	
>=50	3/ 89 (3%)	9/ 86 (10%)	0.2984 (0.0780, 1.1425) /0.077	-7.0943 (-14.5718, 0.3831) /0.063	0.3221 (0.0902, 1.1499) /0.081	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Back pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	1/ 89 (1%)	0/ 86				
Arthralgia						
<35	0/ 84	0/ 98				
35 - <50	5/154 (3%)	2/143 (1%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
<35	0/ 84	2/ 98 (2%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Myalgia						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal pain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	4/154 (3%)	0/143				
>=50	0/ 89	0/ 86				
Muscle contracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms <35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Musculoskeletal chest pain <35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neck pain						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Tendonitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Limb discomfort						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Muscular weakness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Synovial cyst						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pain in jaw						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periarthritis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Plantar fasciitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	8/ 84 (10%)	3/ 98 (3%)	3.3333 (0.8549, 12.9971) /0.083	6.4626 (-0.6815, 13.6067) /0.076	3.1111 (0.8525, 11.3529) /0.086	0.062
35 - <50	3/154 (2%)	7/143 (5%)	0.3860 (0.0979, 1.5224) /0.174	-2.9471 (-7.1029, 1.2088) /0.165	0.3980 (0.1049, 1.5095) /0.176	
>=50	4/ 89 (4%)	5/ 86 (6%)	0.7624 (0.1977, 2.9394) /0.694	-1.3196 (-7.8760, 5.2369) /0.693	0.7730 (0.2147, 2.7830) /0.694	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Rash						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Alopecia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	2/ 89 (2%)	0/ 86				
Dermatitis						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Dermal cyst <35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Hyperhidrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urticaria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Skin fissures						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hand dermatitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lichen sclerosus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Pain of skin						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Rash pruritic						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Skin swelling						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	3/ 84 (4%)	3/ 98 (3%)	1.1728 (0.2304, 5.9712) /0.848	0.5102 (-4.7225, 5.7430) /0.848	1.1667 (0.2419, 5.6277) /0.848	0.395
35 - <50	3/154 (2%)	8/143 (6%)	0.3353 (0.0872, 1.2895) /0.112	-3.6464 (-7.9998, 0.7071) /0.101	0.3482 (0.0942, 1.2870) /0.114	
>=50	1/ 89 (1%)	4/ 86 (5%)	0.2330 (0.0255, 2.1275) /0.197	-3.5276 (-8.4879, 1.4328) /0.163	0.2416 (0.0275, 2.1182) /0.200	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cough						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Oropharyngeal pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Nasal congestion						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rhinitis allergic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	3/143 (2%)				
>=50	0/ 89	0/ 86				
Epistaxis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Dyspnoea						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Sleep apnoea syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoptysis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Nasal discomfort						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	3/ 84 (4%)	3/ 98 (3%)	1.1728 (0.2304, 5.9712) /0.848	0.5102 (-4.7225, 5.7430) /0.848	1.1667 (0.2419, 5.6277) /0.848	0.246
35 - <50	4/154 (3%)	11/143 (8%)	0.3200 (0.0995, 1.0290) /0.056	-5.0949 (-10.1333, -0.0565) /0.047	0.3377 (0.1100, 1.0364) /0.058	
>=50	4/ 89 (4%)	3/ 86 (3%)	1.3020 (0.2827, 5.9958) /0.735	1.0060 (-4.7876, 6.7996) /0.734	1.2884 (0.2970, 5.5885) /0.735	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Headache						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	6/143 (4%)				
>=50	1/ 89 (1%)	2/ 86 (2%)				
Dizziness						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Head discomfort						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Sciatica						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Syncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebral infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Disturbance in attention						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypertonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Neuropathy peripheral						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radiculopathy <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	8/ 84 (10%)	3/ 98 (3%)	3.3333 (0.8549, 12.9971) /0.083	6.4626 (-0.6815, 13.6067) /0.076	3.1111 (0.8525, 11.3529) /0.086	0.310
35 - <50	3/154 (2%)	4/143 (3%)	0.6904 (0.1518, 3.1396) /0.632	-0.8492 (-4.3232, 2.6249) /0.632	0.6964 (0.1586, 3.0580) /0.632	
>=50	4/ 89 (4%)	2/ 86 (2%)	1.9765 (0.3525, 11.0814) /0.439	2.1688 (-3.1860, 7.5236) /0.427	1.9326 (0.3633, 10.2796) /0.440	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Insomnia						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	3/ 89 (3%)	0/ 86				
Anxiety						
<35	5/ 84 (6%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abnormal dreams						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Sleep disorder						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression <35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Panic attack <35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Restlessness						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	4/ 84 (5%)	8/ 98 (8%)	0.5625 (0.1632, 1.9388) /0.362	-3.4014 (-10.4814, 3.6787) /0.346	0.5833 (0.1821, 1.8688) /0.364	0.078
35 - <50	2/154 (1%)	10/143 (7%)	0.1750 (0.0377, 0.8130) /0.026	-5.6943 (-10.2407, -1.1479) /0.014	0.1857 (0.0414, 0.8332) /0.028	
>=50	7/ 89 (8%)	5/ 86 (6%)	1.3829 (0.4216, 4.5367) /0.593	2.0512 (-5.4146, 9.5170) /0.590	1.3528 (0.4464, 4.0996) /0.593	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Limb injury						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Ligament sprain						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Exposure to communicable disease						
<35	2/ 84 (2%)	3/ 98 (3%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Muscle strain						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin laceration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Skin abrasion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod sting						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Heat stroke						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Road traffic accident						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Rib fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury <35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Meniscus injury <35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Wrist fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Burns second degree						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chemical burns of eye						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Clavicle fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Corneal abrasion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Fibula fracture						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Head injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Joint dislocation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scapula fracture						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Investigations						
Any Event						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	1/154 (<1%)	5/143 (3%)				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatine phosphokinase increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Weight increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood cholesterol increased						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Lipase increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

CD4 lymphocytes decreased						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Campylobacter test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased <35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Culture urine positive <35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatic enzyme increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Muscle enzyme increased						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Parasite stool test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Shigella test positive						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Fibrous histiocyoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Hypertension						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure inadequately controlled						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Thrombophlebitis						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	0/ 84	3/ 98 (3%)				
35 - <50	5/154 (3%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Testicular cyst						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cervical dysplasia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermi a						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Penile burning sensation						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile discharge						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Priapism						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prostatitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Testicular torsion						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysuria						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Pollakiuria						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal colic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Leukocyturia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureterolithiasis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Blepharitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis allergic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Blepharospasm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cataract						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Chalazion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diplopia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Eyelid oedema						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Ulcerative keratitis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	1/ 84 (1%)	2/ 98 (2%)				
35 - <50	0/154	0/143				
>=50	0/ 89	2/ 86 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Vitamin D deficiency						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Obesity						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Type 2 diabetes mellitus						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cachexia						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	0/ 84	3/ 98 (3%)				
35 - <50	4/154 (3%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Hypersensitivity						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Food allergy						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	0/143				
>=50	0/ 89	0/ 86				
Drug hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Iron deficiency anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Neutropenia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	1/ 84 (1%)	1/ 98 (1%)				
35 - <50	0/154	1/143 (<1%)				
>=50	3/ 89 (3%)	2/ 86 (2%)				
Palpitations						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tachycardia						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Angina pectoris						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial fibrillation						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cardiac aneurysm						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Jaundice						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial septal defect						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Benign familial pemphigus						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	5/ 84 (6%)	8/ 98 (8%)	0.7120 (0.2238, 2.2656) /0.565	-2.2109 (-9.6262, 5.2045) /0.559	0.7292 (0.2479, 2.1443) /0.566	0.907
35 - <50	9/154 (6%)	14/143 (10%)	0.5719 (0.2395, 1.3656) /0.208	-3.9461 (-10.0658, 2.1737) /0.206	0.5969 (0.2667, 1.3363) /0.210	
>=50	6/ 89 (7%)	11/ 86 (13%)	0.4929 (0.1738, 1.3981) /0.184	-6.0491 (-14.8219, 2.7237) /0.177	0.5271 (0.2039, 1.3622) /0.186	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	0/ 84	4/ 98 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2907 (-28.4646, 15.8832) /0.578	<0.0001 (<0.0001, -) />0.999	0.238
35 - <50	5/154 (3%)	8/143 (6%)	0.5663 (0.1809, 1.7730) /0.329	-2.3477 (-7.0406, 2.3453) /0.327	0.5804 (0.1944, 1.7329) /0.330	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain <35	0/ 84	3/ 98 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3085 (-27.4475, 16.8305) /0.638	<0.0001 (<0.0001, -) />0.999	0.405
35 - <50	4/154 (3%)	8/143 (6%)	0.4500 (0.1325, 1.5281) /0.200	-2.9970 (-7.5245, 1.5305) /0.194	0.4643 (0.1429, 1.5086) /0.202	
>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Pyrexia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Fatigue						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Chest pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hepatitis E						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Epididymitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Anal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erysipelas						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Haemorrhoidal haemorrhage						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oroantral fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Pain in extremity						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Muscle spasms						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Costochondritis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis <35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Depression						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion <35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Transaminases increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tympanic membrane perforation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal colic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Eye disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overall						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Epiglottitis obstructive						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.18

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Age - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	33/ 73 (45%)	25/ 75 (33%)	1.6500 (0.8481, 3.2101) /0.140	11.8721 (-3.7537, 27.4980) /0.136	1.3562 (0.9021, 2.0388) /0.143	0.101
Male	92/254 (36%)	99/252 (39%)	0.8777 (0.6125, 1.2576) /0.477	-3.0652 (-11.5090, 5.3786) /0.477	0.9220 (0.7369, 1.1535) /0.477	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	37/ 73 (51%)	31/ 75 (41%)	1.4588 (0.7620, 2.7928) /0.254	9.3516 (-6.6401, 25.3433) /0.252	1.2262 (0.8624, 1.7436) /0.256	0.413
Male	128/254 (50%)	122/252 (48%)	1.0825 (0.7639, 1.5340) /0.656	1.9810 (-6.7298, 10.6918) /0.656	1.0409 (0.8725, 1.2418) /0.656	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	32/ 73 (44%)	31/ 75 (41%)	1.1078 (0.5772, 2.1260) /0.758	2.5023 (-13.4275, 18.4321) /0.758	1.0605 (0.7294, 1.5420) /0.758	0.970
Male	125/254 (49%)	116/252 (46%)	1.1361 (0.8013, 1.6107) /0.474	3.1809 (-5.5180, 11.8797) /0.474	1.0691 (0.8903, 1.2838) /0.474	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	8/ 73 (11%)	10/ 75 (13%)	0.8000 (0.2969, 2.1556) /0.659	-2.3744 (-12.8880, 8.1392) /0.658	0.8219 (0.3436, 1.9659) /0.659	0.360
Male	19/254 (7%)	37/252 (15%)	0.4698 (0.2622, 0.8419) /0.011	-7.2022 (-12.6394, -1.7651) /0.009	0.5095 (0.3014, 0.8612) /0.012	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
Female	2/ 73 (3%)	2/ 75 (3%)	1.0282 (0.1410, 7.4991) /0.978	0.0731 (-5.1535, 5.2996) /0.978	1.0274 (0.1486, 7.1016) /0.978	0.786
Male	18/254 (7%)	23/252 (9%)	0.7594 (0.3992, 1.4445) /0.402	-2.0404 (-6.7945, 2.7137) /0.400	0.7764 (0.4297, 1.4030) /0.402	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
Female	7/ 73 (10%)	9/ 75 (12%)	0.7778 (0.2735, 2.2115) /0.637	-2.4110 (-12.3964, 7.5745) /0.636	0.7991 (0.3141, 2.0328) /0.638	0.906
Male	12/254 (5%)	16/252 (6%)	0.7314 (0.3388, 1.5791) /0.426	-1.6248 (-5.6087, 2.3591) /0.424	0.7441 (0.3593, 1.5408) /0.426	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia Female	3/ 73 (4%)	2/ 75 (3%)	1.5643 (0.2537, 9.6448) /0.630	1.4429 (-4.3907, 7.2766) /0.628	1.5411 (0.2652, 8.9569) /0.630	0.232
Male	12/254 (5%)	24/252 (10%)	0.4711 (0.2302, 0.9641) /0.039	-4.7994 (-9.2651, -0.3337) /0.035	0.4961 (0.2537, 0.9701) /0.040	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
Female	5/ 73 (7%)	4/ 75 (5%)	1.3051 (0.3363, 5.0658) /0.700	1.5160 (-6.1934, 9.2254) /0.700	1.2842 (0.3590, 4.5945) /0.700	0.746
Male	9/254 (4%)	9/252 (4%)	0.9918 (0.3871, 2.5412) /0.986	-0.0281 (-3.2559, 3.1997) /0.986	0.9921 (0.4004, 2.4582) /0.986	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue Female	1/ 73 (1%)	1/ 75 (1%)	1.0278 (0.0631, 16.7455) /0.985	0.0365 (-3.6848, 3.7578) /0.985	1.0274 (0.0655, 16.1197) /0.985	0.389
Male	5/254 (2%)	18/252 (7%)	0.2610 (0.0954, 0.7144) /0.009	-5.1744 (-8.7840, -1.5647) /0.005	0.2756 (0.1039, 0.7309) /0.010	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
Female	1/ 73 (1%)	7/ 75 (9%)	0.1349 (0.0162, 1.1256) /0.064	-7.9635 (-15.0665, -0.8605) /0.028	0.1468 (0.0185, 1.1636) /0.069	0.187
Male	5/254 (2%)	8/252 (3%)	0.6124 (0.1976, 1.8982) /0.396	-1.2061 (-3.9637, 1.5515) /0.391	0.6201 (0.2056, 1.8697) /0.396	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
Female	2/ 73 (3%)	5/ 75 (7%)	0.3944 (0.0740, 2.1007) /0.276	-3.9269 (-10.7013, 2.8474) /0.256	0.4110 (0.0823, 2.0515) /0.278	0.279
Male	7/254 (3%)	6/252 (2%)	1.1619 (0.3850, 3.5068) /0.790	0.3750 (-2.3812, 3.1311) /0.790	1.1575 (0.3945, 3.3962) /0.790	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia Female	5/ 73 (7%)	2/ 75 (3%)	2.6838 (0.5038, 14.2964) /0.247	4.1826 (-2.6634, 11.0287) /0.231	2.5685 (0.5145, 12.8221) /0.250	0.596
Male	6/254 (2%)	4/252 (2%)	1.5000 (0.4182, 5.3806) /0.534	0.7749 (-1.6478, 3.1976) /0.531	1.4882 (0.4251, 5.2104) /0.534	
Chills Female	1/ 73 (1%)	1/ 75 (1%)	1.0278 (0.0631, 16.7455) /0.985	0.0365 (-3.6848, 3.7578) /0.985	1.0274 (0.0655, 16.1197) /0.985	0.805
Male	9/254 (4%)	6/252 (2%)	1.5061 (0.5281, 4.2955) /0.444	1.1624 (-1.7893, 4.1140) /0.440	1.4882 (0.5376, 4.1196) /0.444	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
Female	0/ 73	6/ 75 (8%)				
Male	4/254 (2%)	5/252 (2%)				
Injection site bruising						
Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.357
Male	7/254 (3%)	4/252 (2%)	1.7571 (0.5079, 6.0781) /0.373	1.1686 (-1.3680, 3.7052) /0.367	1.7362 (0.5146, 5.8577) /0.374	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.186
Male	4/254 (2%)	6/252 (2%)	0.6560 (0.1829, 2.3531) /0.518	-0.8061 (-3.2325, 1.6202) /0.515	0.6614 (0.1889, 2.3157) /0.518	
Pain Female	0/ 73	0/ 75				
Male	2/254 (<1%)	7/252 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	6/252 (2%)				
Discomfort						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Injection site anaesthesia						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Chest pain						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Feeling hot						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Injection site papule						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vessel puncture site haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Chest discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic fatigue syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gait disturbance						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Induration						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Inflammation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Non-cardiac chest pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Peripheral swelling						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sluggishness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Thirst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Xerosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	20/ 73 (27%)	24/ 75 (32%)	0.8019 (0.3954, 1.6262) /0.541	-4.6027 (-19.3040, 10.0985) /0.539	0.8562 (0.5202, 1.4092) /0.541	0.927
Male	85/254 (33%)	96/252 (38%)	0.8173 (0.5679, 1.1763) /0.277	-4.6307 (-12.9748, 3.7134) /0.277	0.8784 (0.6950, 1.1102) /0.278	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	6/ 73 (8%)	11/ 75 (15%)	0.5210 (0.1820, 1.4920) /0.225	-6.4475 (-16.6357, 3.7408) /0.215	0.5604 (0.2187, 1.4362) /0.228	0.311
Male	29/254 (11%)	30/252 (12%)	0.9538 (0.5541, 1.6417) /0.864	-0.4874 (-6.0806, 5.1057) /0.864	0.9591 (0.5936, 1.5495) /0.864	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	3/ 73 (4%)	5/ 75 (7%)	0.6000 (0.1381, 2.6074) /0.496	-2.5571 (-9.8101, 4.6960) /0.490	0.6164 (0.1528, 2.4863) /0.497	0.975
Male	21/254 (8%)	33/252 (13%)	0.5981 (0.3358, 1.0655) /0.081	-4.8275 (-10.1958, 0.5407) /0.078	0.6314 (0.3759, 1.0605) /0.082	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
Female	2/ 73 (3%)	1/ 75 (1%)	2.0845 (0.1849, 23.4993) /0.552	1.4064 (-3.1500, 5.9628) /0.545	2.0548 (0.1904, 22.1736) /0.553	0.282
Male	7/254 (3%)	13/252 (5%)	0.5210 (0.2044, 1.3283) /0.172	-2.4028 (-5.7957, 0.9900) /0.165	0.5342 (0.2167, 1.3168) /0.173	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis Female	2/ 73 (3%)	2/ 75 (3%)	1.0282 (0.1410, 7.4991) /0.978	0.0731 (-5.1535, 5.2996) /0.978	1.0274 (0.1486, 7.1016) /0.978	0.519
Male	5/254 (2%)	10/252 (4%)	0.4859 (0.1637, 1.4424) /0.194	-1.9998 (-4.9540, 0.9545) /0.185	0.4961 (0.1720, 1.4308) /0.195	
Syphilis Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	5/254 (2%)	10/252 (4%)	0.4859 (0.1637, 1.4424) /0.194	-1.9998 (-4.9540, 0.9545) /0.185	0.4961 (0.1720, 1.4308) /0.195	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	3/ 73 (4%)	2/ 75 (3%)				
Male	3/254 (1%)	6/252 (2%)				
Gonorrhoea Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	8/254 (3%)	6/252 (2%)	1.3333 (0.4559, 3.8994) /0.599	0.7687 (-2.0873, 3.6246) /0.598	1.3228 (0.4657, 3.7578) /0.599	
Influenza Female	1/ 73 (1%)	2/ 75 (3%)				
Male	5/254 (2%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis Female	0/ 73	1/ 75 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6076 (-27.5142, 20.2991) /0.767	<0.0001 (<0.0001, -) />0.999	0.290
Male	5/254 (2%)	6/252 (2%)	0.8233 (0.2480, 2.7329) /0.751	-0.4124 (-2.9544, 2.1295) /0.750	0.8268 (0.2556, 2.6744) /0.751	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	6/254 (2%)	4/252 (2%)	1.5000 (0.4182, 5.3806) /0.534	0.7749 (-1.6478, 3.1976) /0.531	1.4882 (0.4251, 5.2104) /0.534	
Respiratory tract infection						
Female	3/ 73 (4%)	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	5/252 (2%)				
Rhinitis						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
Female	0/ 73	3/ 75 (4%)				
Male	2/254 (<1%)	3/252 (1%)				
Urinary tract infection						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Oral herpes						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	4/252 (2%)				
Viral infection						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	5/252 (2%)				
Folliculitis						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tonsillitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Herpes simplex						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Hordeolum						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				
Ear infection						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Fungal skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Gingivitis						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Herpes zoster						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	3/252 (1%)				
Proctitis gonococcal						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Tooth infection						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Lower respiratory tract infection						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Secondary syphilis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Tooth abscess						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Vaginal infection						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Body tinea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Lymphogranuloma venereum						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Mycoplasma genitalium infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Oropharyngeal gonococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Paronychia						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Pneumonia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Postoperative wound infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Skin infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tinea infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Acarodermatitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod infestation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Bronchitis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cellulitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Chronic sinusitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cutaneous blastomycosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Cystitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Enteritis infectious						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterovirus infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Erythema migrans						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
External ear cellulitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis viral						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Genital herpes						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gingival abscess						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hepatitis E						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Infectious mononucleosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Labyrinthitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Laryngitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Otitis media acute						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pericoronitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Peritonsillar abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pharyngitis bacterial						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pharyngitis streptococcal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Primary syphilis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pulpitis dental						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Schistosomiasis cutaneous						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Syphilis genital						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea capitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tinea cruris						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tinea pedis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tracheobronchitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Trichomoniasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Varicella						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Viral rash						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rhinitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	8/ 73 (11%)	10/ 75 (13%)	0.8000 (0.2969, 2.1556) /0.659	-2.3744 (-12.8880, 8.1392) /0.658	0.8219 (0.3436, 1.9659) /0.659	0.912
Male	44/254 (17%)	56/252 (22%)	0.7333 (0.4722, 1.1389) /0.167	-4.8994 (-11.8282, 2.0294) /0.166	0.7795 (0.5470, 1.1110) /0.168	

Note: "Any Event" represents subjects with any AE reported.

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Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea Female	2/ 73 (3%)	2/ 75 (3%)	1.0282 (0.1410, 7.4991) /0.978	0.0731 (-5.1535, 5.2996) /0.978	1.0274 (0.1486, 7.1016) /0.978	0.937
Male	18/254 (7%)	16/252 (6%)	1.1250 (0.5602, 2.2591) /0.741	0.7374 (-3.6240, 5.0989) /0.740	1.1161 (0.5824, 2.1391) /0.741	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea Female	0/ 73	3/ 75 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2123 (-30.1066, 17.6820) /0.610	<0.0001 (<0.0001, -) />0.999	0.199
Male	5/254 (2%)	14/252 (6%)	0.3414 (0.1211, 0.9624) /0.042	-3.5871 (-6.8911, -0.2830) /0.033	0.3543 (0.1296, 0.9691) /0.043	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
Female	0/ 73	1/ 75 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6076 (-27.5142, 20.2991) /0.767	<0.0001 (<0.0001, -) />0.999	0.257
Male	6/254 (2%)	6/252 (2%)	0.9919 (0.3156, 3.1179) /0.989	-0.0187 (-2.6704, 2.6329) /0.989	0.9921 (0.3243, 3.0349) /0.989	
Abdominal pain						
Female	2/ 73 (3%)	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	7/252 (3%)				
Constipation						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	6/252 (2%)				
Abdominal distension						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Toothache						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				
Vomiting						
Female	0/ 73	2/ 75 (3%)				
Male	3/254 (1%)	1/252 (<1%)				
Abdominal pain upper						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	2/252 (<1%)				
Abdominal discomfort						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Anogenital dysplasia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Flatulence						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Dry mouth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Gingival pain						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Irritable bowel syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective gingivitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Rectal discharge						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Abdominal hernia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal tenderness						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal fistula						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Anal pruritus						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cheilitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Dental caries						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Food poisoning						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastric disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gingival hypertrophy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Haematemesis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hiatus hernia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Hypertrophic anal papilla						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Large intestine polyp						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Oesophagitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pancreatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Perianal erythema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Proctalgia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tooth disorder						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	9/ 73 (12%)	9/ 75 (12%)	1.0312 (0.3848, 2.7638) /0.951	0.3288 (-10.2053, 10.8628) /0.951	1.0274 (0.4322, 2.4423) /0.951	0.473
Male	32/254 (13%)	44/252 (17%)	0.6814 (0.4162, 1.1157) /0.127	-4.8619 (-11.0766, 1.3528) /0.125	0.7215 (0.4738, 1.0989) /0.128	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain Female	3/ 73 (4%)	4/ 75 (5%)	0.7607 (0.1642, 3.5234) /0.727	-1.2237 (-8.0500, 5.6025) /0.725	0.7705 (0.1786, 3.3241) /0.727	0.991
Male	10/254 (4%)	13/252 (5%)	0.7535 (0.3242, 1.7514) /0.511	-1.2217 (-4.8519, 2.4084) /0.509	0.7632 (0.3409, 1.7083) /0.511	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia Female	3/ 73 (4%)	3/ 75 (4%)	1.0286 (0.2008, 5.2695) /0.973	0.1096 (-6.2469, 6.4661) /0.973	1.0274 (0.2143, 4.9261) /0.973	0.859
Male	7/254 (3%)	8/252 (3%)	0.8644 (0.3087, 2.4204) /0.781	-0.4187 (-3.3748, 2.5375) /0.781	0.8681 (0.3196, 2.3581) /0.781	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	0/ 73	1/ 75 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6076 (-27.5142, 20.2991) /0.767	<0.0001 (<0.0001, -) />0.999	0.298
Male	7/254 (3%)	9/252 (4%)	0.7652 (0.2805, 2.0872) /0.601	-0.8155 (-3.8656, 2.2345) /0.600	0.7717 (0.2919, 2.0401) /0.601	
Myalgia						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	6/254 (2%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				
Muscle contracture						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	2/252 (<1%)				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	0/254	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Neck pain						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Tendonitis						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bursitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Intervertebral disc protrusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Arthritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Arthropathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical spinal stenosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Exostosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Femoroacetabular impingement						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Flank pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Joint stiffness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Limb discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Muscular weakness						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Musculoskeletal stiffness						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Osteopenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rotator cuff syndrome						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scoliosis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Spinal osteoarthritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Synovial cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Temporomandibular joint syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tenosynovitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Trigger finger						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	7/ 73 (10%)	10/ 75 (13%)	0.6894 (0.2474, 1.9210) /0.477	-3.7443 (-13.9819, 6.4933) /0.473	0.7192 (0.2893, 1.7876) /0.478	0.809
Male	32/254 (13%)	39/252 (15%)	0.7872 (0.4756, 1.3030) /0.352	-2.8778 (-8.9270, 3.1715) /0.351	0.8141 (0.5275, 1.2562) /0.353	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.447
Male	7/254 (3%)	5/252 (2%)	1.4000 (0.4384, 4.4709) /0.570	0.7718 (-1.8773, 3.4209) /0.568	1.3890 (0.4467, 4.3185) /0.570	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash						
Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.809
Male	5/254 (2%)	7/252 (3%)	0.7028 (0.2201, 2.2444) /0.552	-0.8093 (-3.4617, 1.8431) /0.550	0.7087 (0.2279, 2.2033) /0.552	
Eczema						
Female	1/ 73 (1%)	3/ 75 (4%)				
Male	2/254 (<1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia						
Female	3/ 73 (4%)	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				
Acne						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	4/252 (2%)				
Skin lesion						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Seborrhoeic dermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Night sweats						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dermal cyst						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Dermatitis contact						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Dry skin						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Rash erythematous						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Skin exfoliation						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin mass						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Urticaria						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Androgenetic alopecia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chloasma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Cold sweat						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dermatitis atopic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug eruption						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Ecchymosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eczema asteatotic						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intertrigo Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Keratosis pilaris Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Macule						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Miliaria						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nail bed inflammation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Petechiae						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pigmentation disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pityriasis rosea Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pruritus generalised Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psoriasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Purpura						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rash morbilliform						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin discolouration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin fissures						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin hypertrophy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Skin irritation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Solar dermatitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	8/ 73 (11%)	11/ 75 (15%)	0.7161 (0.2704, 1.8964) /0.502	-3.7078 (-14.4527, 7.0371) /0.499	0.7472 (0.3188, 1.7513) /0.503	0.799
Male	24/254 (9%)	28/252 (11%)	0.8348 (0.4695, 1.4841) /0.538	-1.6623 (-6.9534, 3.6288) /0.538	0.8504 (0.5073, 1.4255) /0.539	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	3/ 73 (4%)	6/ 75 (8%)	0.4929 (0.1185, 2.0497) /0.331	-3.8904 (-11.5347, 3.7538) /0.319	0.5137 (0.1334, 1.9774) /0.333	0.617
Male	10/254 (4%)	13/252 (5%)	0.7535 (0.3242, 1.7514) /0.511	-1.2217 (-4.8519, 2.4084) /0.509	0.7632 (0.3409, 1.7083) /0.511	
Oropharyngeal pain						
Female	5/ 73 (7%)	3/ 75 (4%)				
Male	2/254 (<1%)	6/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinus congestion						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	4/252 (2%)				
Nasal congestion						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	2/252 (<1%)				
Epistaxis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Asthma						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Catarrh						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Dyspnoea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Oropharyngeal discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Rales						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Rhinorrhoea						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Bronchospasm						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Dry throat						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoptysis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Interstitial lung disease						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Nasal oedema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal septum deviation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Painful respiration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pleuritic pain						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Respiratory disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract congestion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	4/ 73 (5%)	6/ 75 (8%)	0.6667 (0.1802, 2.4669) /0.544	-2.5205 (-10.5798, 5.5387) /0.540	0.6849 (0.2015, 2.3279) /0.544	0.509
Male	30/254 (12%)	28/252 (11%)	1.0714 (0.6198, 1.8521) /0.805	0.6999 (-4.8506, 6.2505) /0.805	1.0630 (0.6547, 1.7259) /0.805	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	3/ 73 (4%)	3/ 75 (4%)	1.0286 (0.2008, 5.2695) /0.973	0.1096 (-6.2469, 6.4661) /0.973	1.0274 (0.2143, 4.9261) /0.973	0.969
Male	15/254 (6%)	14/252 (6%)	1.0669 (0.5039, 2.2590) /0.866	0.3500 (-3.7000, 4.3999) /0.866	1.0630 (0.5241, 2.1561) /0.866	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness Female	0/ 73	1/ 75 (1%)	<0.0001 (<0.0001, -) />0.999	-3.6076 (-27.5142, 20.2991) /0.767	<0.0001 (<0.0001, -) />0.999	0.175
Male	10/254 (4%)	6/252 (2%)	1.6803 (0.6014, 4.6949) /0.322	1.5561 (-1.4875, 4.5996) /0.316	1.6535 (0.6101, 4.4814) /0.323	
Paraesthesia Female	1/ 73 (1%)	1/ 75 (1%)				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Presyncope Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	0/252				
Somnolence Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Amnesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Burning sensation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cervical radiculopathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dysarthria						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Head discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hyperaesthesia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersomnia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypoaesthesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Muscle contractions involuntary						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Polyneuropathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tension headache						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	1/ 73 (1%)	4/ 75 (5%)	0.2465 (0.0269, 2.2601) /0.215	-3.9635 (-9.7054, 1.7785) /0.176	0.2568 (0.0294, 2.2439) /0.219	0.380
Male	19/254 (7%)	29/252 (12%)	0.6217 (0.3389, 1.1406) /0.125	-4.0276 (-9.1257, 1.0705) /0.122	0.6500 (0.3744, 1.1285) /0.126	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.782
Male	5/254 (2%)	14/252 (6%)	0.3414 (0.1211, 0.9624) /0.042	-3.5871 (-6.8911, -0.2830) /0.033	0.3543 (0.1296, 0.9691) /0.043	
Anxiety Female	0/ 73	0/ 75				
Male	3/254 (1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abnormal dreams						
Female	0/ 73	0/ 75				
Male	0/254	4/252 (2%)				
Depressed mood						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Nightmare						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Sleep disorder						
Female	0/ 73	0/ 75				
Male	0/254	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Drug abuse						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Irritability						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Adjustment disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Adjustment disorder with mixed anxiety and depressed mood						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Agoraphobia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Emotional distress						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Loss of libido						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Mood swings						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Nervousness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic stress disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Stress						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	2/ 73 (3%)	5/ 75 (7%)	0.3944 (0.0740, 2.1007) /0.276	-3.9269 (-10.7013, 2.8474) /0.256	0.4110 (0.0823, 2.0515) /0.278	0.891
Male	14/254 (6%)	30/252 (12%)	0.4317 (0.2231, 0.8353) /0.013	-6.3930 (-11.2780, -1.5079) /0.010	0.4630 (0.2516, 0.8521) /0.013	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	4/252 (2%)				
Limb injury						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	2/252 (<1%)				
Contusion						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Exposure to communicable disease						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	3/252 (1%)				
Skin laceration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Animal bite						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Arthropod sting						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Bone contusion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Concussion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Epicondylitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Fall						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Heat stroke						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection related reaction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury corneal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lip injury						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nail injury						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Road traffic accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sunburn						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Traumatic haematoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Ulna fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 73	5/ 75 (7%)	<0.0001 (<0.0001, -) />0.999	-8.7632 (-32.8147, 15.2884) /0.475	<0.0001 (<0.0001, -) />0.999	0.015
Male	14/254 (6%)	15/252 (6%)	0.9217 (0.4353, 1.9514) /0.831	-0.4406 (-4.4915, 3.6104) /0.831	0.9260 (0.4565, 1.8782) /0.831	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
Female	0/ 73	2/ 75 (3%)				
Male	1/254 (<1%)	4/252 (2%)				
Blood pressure increased						
Female	0/ 73	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Blood creatine phosphokinase increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Blood cholesterol increased						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Low density lipoprotein increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Aspartate aminotransferase increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blood bilirubin unconjugated increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Blood triglycerides increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Escherichia test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Haemoglobin increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intraocular pressure increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Vitamin D decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)	1.0278 (0.0631, 16.7455) /0.985	0.0365 (-3.6848, 3.7578) /0.985	1.0274 (0.0655, 16.1197) /0.985	0.625
Male	7/254 (3%)	14/252 (6%)	0.4818 (0.1911, 1.2145) /0.122	-2.7997 (-6.2712, 0.6719) /0.114	0.4961 (0.2036, 1.2085) /0.123	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	6/252 (2%)				
Skin papilloma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	5/252 (2%)				
Acrochordon						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Basal cell carcinoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Fibroma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Fibrous histiocyctoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lipoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Lipoma of breast						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral papilloma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Uterine leiomyoma						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	3/ 73 (4%)	4/ 75 (5%)	0.7607 (0.1642, 3.5234) /0.727	-1.2237 (-8.0500, 5.6025) /0.725	0.7705 (0.1786, 3.3241) /0.727	0.668
Male	8/254 (3%)	7/252 (3%)	1.1382 (0.4065, 3.1872) /0.805	0.3718 (-2.5829, 3.3265) /0.805	1.1339 (0.4174, 3.0800) /0.805	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	6/254 (2%)	3/252 (1%)				
Flushing						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Haematoma						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Hot flush						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hypotension						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral coldness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Varicose vein						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	3/ 73 (4%)	1/ 75 (1%)	3.1714 (0.3222, 31.2127) /0.323	2.7763 (-2.4654, 8.0179) /0.299	3.0822 (0.3281, 28.9553) /0.325	0.236
Male	7/254 (3%)	9/252 (4%)	0.7652 (0.2805, 2.0872) /0.601	-0.8155 (-3.8656, 2.2345) /0.600	0.7717 (0.2919, 2.0401) /0.601	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Prostatomegaly						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Balanoposthitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Breast pain						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Genital erythema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Penile pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Testicular cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular mass						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Testicular pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testis discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Uterine polyp						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Vaginal discharge						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.685
Male	7/254 (3%)	8/252 (3%)	0.8644 (0.3087, 2.4204) /0.781	-0.4187 (-3.3748, 2.5375) /0.781	0.8681 (0.3196, 2.3581) /0.781	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Vertigo						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Cerumen impaction						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Excessive cerumen production						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deafness neurosensory						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypoacusis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
Female	1/ 73 (1%)	4/ 75 (5%)	0.2465 (0.0269, 2.2601) /0.215	-3.9635 (-9.7054, 1.7785) /0.176	0.2568 (0.0294, 2.2439) /0.219	0.771
Male	3/254 (1%)	8/252 (3%)	0.3645 (0.0956, 1.3902) /0.140	-1.9935 (-4.5334, 0.5464) /0.124	0.3720 (0.0998, 1.3864) /0.141	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Micturition urgency						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Nocturia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Micturition disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nephrolithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pollakiuria						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Urethral disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract disorder						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.398
Male	2/254 (<1%)	9/252 (4%)	0.2143 (0.0458, 1.0018) /0.050	-2.7840 (-5.3200, -0.2480) /0.031	0.2205 (0.0481, 1.0103) /0.052	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Conjunctivitis allergic						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Dry eye						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Eyelid cyst						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Glaucoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Mydriasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ocular hyperaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Vision blurred						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Vitreous floaters						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	1/ 73 (1%)	4/ 75 (5%)				
Male	4/254 (2%)	4/252 (2%)				
Decreased appetite						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Vitamin D deficiency						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gluten sensitivity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gout						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hyperglycaemia						
a						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hypokalaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Obesity						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Immune system disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)				
Male	7/254 (3%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
Female	0/ 73	2/ 75 (3%)				
Male	5/254 (2%)	1/252 (<1%)				
Hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Anaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Lymph node pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Endocrine disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypogonadism						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Goitre						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Palpitations						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tachycardia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Hepatobiliary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hepatomegaly						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				
Menopause						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stress at work						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Congenital, familial and genetic disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type V hyperlipidaemia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	25/ 73 (34%)	35/ 75 (47%)	0.5952 (0.3067, 1.1550) /0.125	-12.4201 (-28.1037, 3.2636) /0.121	0.7339 (0.4922, 1.0942) /0.129	0.055
Male	131/254 (52%)	116/252 (46%)	1.2487 (0.8807, 1.7705) /0.213	5.5431 (-3.1542, 14.2403) /0.212	1.1204 (0.9367, 1.3402) /0.213	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
General disorders and administration site conditions						
Any Event						
Female	17/ 73 (23%)	22/ 75 (29%)	0.7313 (0.3503, 1.5267) /0.405	-6.0457 (-20.1942, 8.1028) /0.402	0.7939 (0.4605, 1.3688) /0.406	0.296
Male	90/254 (35%)	82/252 (33%)	1.1377 (0.7873, 1.6441) /0.492	2.8934 (-5.3566, 11.1434) /0.492	1.0889 (0.8538, 1.3888) /0.492	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	16/ 73 (22%)	18/ 75 (24%)	0.8889 (0.4128, 1.9140) /0.763	-2.0822 (-15.6278, 11.4634) /0.763	0.9132 (0.5056, 1.6497) /0.764	0.548
Male	83/254 (33%)	74/252 (29%)	1.1675 (0.8007, 1.7024) /0.421	3.3121 (-4.7434, 11.3675) /0.420	1.1128 (0.8576, 1.4438) /0.421	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
Female	2/ 73 (3%)	8/ 75 (11%)	0.2359 (0.0483, 1.1511) /0.074	-7.9269 (-15.8534, -0.0005) /0.050	0.2568 (0.0564, 1.1692) /0.079	0.645
Male	1/254 (<1%)	7/252 (3%)	0.1383 (0.0169, 1.1327) /0.065	-2.3841 (-4.5543, -0.2139) /0.031	0.1417 (0.0176, 1.1436) /0.067	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
Female	0/ 73	1/ 75 (1%)				
Male	5/254 (2%)	2/252 (<1%)				
Injection site induration						
Female	2/ 73 (3%)	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	5/254 (2%)	8/252 (3%)	0.6124 (0.1976, 1.8982) /0.396	-1.2061 (-3.9637, 1.5515) /0.391	0.6201 (0.2056, 1.8697) /0.396	
Injection site swelling						
Female	5/ 73 (7%)	2/ 75 (3%)				
Male	3/254 (1%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	4/252 (2%)				
Injection site pruritus						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Injection site erythema						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	0/252				
Chills						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Influenza like illness						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	1/252 (<1%)				
Malaise						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Injection site reaction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Chest pain						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Nodule						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Vessel puncture site haematoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gait disturbance						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Peripheral swelling						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discharge						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Injection site fibrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site hypersensitivity						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injection site necrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	11/ 73 (15%)	19/ 75 (25%)	0.5229 (0.2290, 1.1942) /0.124	-10.2648 (-23.0801, 2.5504) /0.116	0.5948 (0.3047, 1.1612) /0.128	0.203
Male	55/254 (22%)	57/252 (23%)	0.9455 (0.6214, 1.4388) /0.794	-0.9655 (-8.2000, 6.2690) /0.794	0.9573 (0.6904, 1.3275) /0.794	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
Female	2/ 73 (3%)	0/ 75	>999 (>999, >999) /NC	4.9973 (-18.5796, 28.5743) /0.678	>999 (>999, >999) /NC	0.145
Male	11/254 (4%)	8/252 (3%)	1.3807 (0.5459, 3.4919) /0.496	1.1561 (-2.1532, 4.4654) /0.494	1.3642 (0.5580, 3.3349) /0.496	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
Female	1/ 73 (1%)	6/ 75 (8%)	0.1597 (0.0187, 1.3611) /0.093	-6.6301 (-13.3240, 0.0637) /0.052	0.1712 (0.0211, 1.3876) /0.098	0.065
Male	10/254 (4%)	9/252 (4%)	1.1066 (0.4419, 2.7708) /0.829	0.3656 (-2.9465, 3.6776) /0.829	1.1024 (0.4556, 2.6671) /0.829	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Female	0/ 73	4/ 75 (5%)				
Male	2/254 (<1%)	5/252 (2%)				
Pharyngitis						
Female	0/ 73	1/ 75 (1%)				
Male	4/254 (2%)	5/252 (2%)				
Syphilis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	6/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis Female	0/ 73	1/ 75 (1%)				
Male	5/254 (2%)	2/252 (<1%)				
Gonorrhoea Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				
Influenza Female	2/ 73 (3%)	2/ 75 (3%)				
Male	1/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinusitis						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Chlamydial infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Respiratory tract infection viral						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Urinary tract infection						
Female	0/ 73	3/ 75 (4%)				
Male	1/254 (<1%)	1/252 (<1%)				
Oral herpes						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Viral infection						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Folliculitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Tinea versicolour						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastroenteritis viral						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Herpes zoster						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	6/252 (2%)				
Furuncle						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tooth abscess						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Anal chlamydia infection						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Mycoplasma genitalium infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Oropharyngeal gonococcal infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pneumonia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Viral pharyngitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Cellulitis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Cystitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Enteritis infectious						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia urinary tract infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Genital herpes						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pharyngeal chlamydia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pharyngotonsillitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pulpitis dental						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Tracheitis						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Varicella						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Urethritis chlamydial						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Shigella infection Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Abscess Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Asymptomatic bacteriuria						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Bacterial diarrhoea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial rhinitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Bacterial vaginosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest wall abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Dermatophytosis of nail						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Device related infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Diarrhoea infectious						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear infection bacterial						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Enterobiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Epididymitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia infection						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastroenteritis Escherichia coli						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Genitourinary tract infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Lice infestation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Oesophageal candidiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ophthalmic herpes zoster						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Perirectal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pulmonary tuberculosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Sialoadenitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin bacterial infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Subcutaneous abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vulvovaginal mycotic infection						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	1/ 73 (1%)	4/ 75 (5%)	0.2465 (0.0269, 2.2601) /0.215	-3.9635 (-9.7054, 1.7785) /0.176	0.2568 (0.0294, 2.2439) /0.219	0.331
Male	16/254 (6%)	22/252 (9%)	0.7028 (0.3600, 1.3721) /0.302	-2.4309 (-7.0215, 2.1596) /0.299	0.7215 (0.3882, 1.3412) /0.302	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	5/254 (2%)	6/252 (2%)	0.8233 (0.2480, 2.7329) /0.751	-0.4124 (-2.9544, 2.1295) /0.750	0.8268 (0.2556, 2.6744) /0.751	
Nausea						
Female	0/ 73	1/ 75 (1%)				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Abdominal pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Haemorrhoids						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Constipation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Abdominal distension						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Toothache						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
Female	0/ 73	0/ 75				
Male	3/254 (1%)	0/252				
Abdominal pain upper						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrooesophageal reflux disease						
Female	0/ 73	0/ 75				
Male	0/254	4/252 (2%)				
Abdominal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Gastritis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Inguinal hernia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fistula						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Colitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Anal fissure						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Crohn's disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gingival ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Glossitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids thrombosed						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intestinal polyp						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontal disease						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Proctitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Tongue ulceration						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
Female	4/ 73 (5%)	7/ 75 (9%)	0.5631 (0.1576, 2.0119) /0.377	-3.8539 (-12.2561, 4.5483) /0.369	0.5871 (0.1794, 1.9210) /0.379	0.444
Male	16/254 (6%)	16/252 (6%)	0.9916 (0.4846, 2.0290) /0.982	-0.0500 (-4.2916, 4.1916) /0.982	0.9921 (0.5073, 1.9402) /0.982	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
Female	1/ 73 (1%)	2/ 75 (3%)				
Male	2/254 (<1%)	1/252 (<1%)				
Arthralgia						
Female	1/ 73 (1%)	0/ 75				
Male	5/254 (2%)	4/252 (2%)				
Pain in extremity						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Musculoskeletal pain						
Female	0/ 73	0/ 75				
Male	5/254 (2%)	0/252				
Muscle contracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Musculoskeletal chest pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Neck pain						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Exostosis						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Limb discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rotator cuff syndrome						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Synovial cyst						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Groin pain						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pain in jaw						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periarthritis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Plantar fasciitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	4/ 73 (5%)	3/ 75 (4%)	1.3913 (0.3004, 6.4441) /0.673	1.4795 (-5.3706, 8.3295) /0.672	1.3699 (0.3175, 5.9095) /0.673	0.628
Male	11/254 (4%)	12/252 (5%)	0.9054 (0.3919, 2.0916) /0.816	-0.4312 (-4.0615, 3.1991) /0.816	0.9094 (0.4089, 2.0227) /0.816	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Rash						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Eczema						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Skin lesion						
Female	1/ 73 (1%)	0/ 75				
Male	2/254 (<1%)	0/252				
Dermatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Dermal cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Dermatitis contact						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Urticaria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Skin fissures						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hand dermatitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lichen sclerosus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Pain of skin						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rash pruritic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash vesicular						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Skin swelling						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	1/ 73 (1%)	2/ 75 (3%)	0.5069 (0.0450, 5.7149) /0.583	-1.2968 (-5.8139, 3.2203) /0.574	0.5137 (0.0476, 5.5434) /0.583	0.930
Male	6/254 (2%)	13/252 (5%)	0.4448 (0.1663, 1.1893) /0.106	-2.7965 (-6.1051, 0.5120) /0.098	0.4579 (0.1768, 1.1858) /0.108	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Oropharyngeal pain						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Sinus congestion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Rhinitis allergic						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Epistaxis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Dyspnoea						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Productive cough						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Haemoptysis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Nasal discomfort						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	0/ 73	5/ 75 (7%)	<0.0001 (<0.0001, -) />0.999	-8.7632 (-32.8147, 15.2884) /0.475	<0.0001 (<0.0001, -) />0.999	0.017
Male	11/254 (4%)	12/252 (5%)	0.9054 (0.3919, 2.0916) /0.816	-0.4312 (-4.0615, 3.1991) /0.816	0.9094 (0.4089, 2.0227) /0.816	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache Female	0/ 73	3/ 75 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2123 (-30.1066, 17.6820) /0.610	<0.0001 (<0.0001, -) />0.999	0.130
Male	4/254 (2%)	7/252 (3%)	0.5600 (0.1619, 1.9372) /0.360	-1.2030 (-3.7448, 1.3389) /0.354	0.5669 (0.1680, 1.9127) /0.360	
Dizziness Female	0/ 73	3/ 75 (4%)				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
Head discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hypoaesthesia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tension headache						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Syncope						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral infarction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Disturbance in attention						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hypertonia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Radiculopathy						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.040
Male	15/254 (6%)	7/252 (3%)	2.1967 (0.8801, 5.4828) /0.092	3.1277 (-0.4107, 6.6662) /0.083	2.1260 (0.8818, 5.1259) /0.093	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
Female	0/ 73	1/ 75 (1%)				
Male	5/254 (2%)	1/252 (<1%)				
Anxiety						
Female	0/ 73	0/ 75				
Male	6/254 (2%)	3/252 (1%)				
Abnormal dreams						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Depression						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	3/252 (1%)				
Panic attack						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Restlessness						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
Female	1/ 73 (1%)	6/ 75 (8%)	0.1597 (0.0187, 1.3611) /0.093	-6.6301 (-13.3240, 0.0637) /0.052	0.1712 (0.0211, 1.3876) /0.098	0.158
Male	12/254 (5%)	17/252 (7%)	0.6855 (0.3204, 1.4664) /0.330	-2.0216 (-6.0710, 2.0277) /0.328	0.7003 (0.3415, 1.4361) /0.331	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Limb injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Exposure to communicable disease						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Skin laceration						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Skin abrasion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
Female	0/ 73	2/ 75 (3%)				
Male	0/254	0/252				
Heat stroke						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Road traffic accident						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rib fracture						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Joint injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Wrist fracture						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burns second degree						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Chemical burns of eye						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Corneal abrasion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibula fracture						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Head injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Joint dislocation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scapula fracture						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 73	0/ 75	NC	NC	NC	>0.999
Male	2/254 (<1%)	9/252 (4%)	0.2143 (0.0458, 1.0018) /0.050	-2.7840 (-5.3200, -0.2480) /0.031	0.2205 (0.0481, 1.0103) /0.052	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blood creatine phosphokinase increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Blood cholesterol increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				
CD4 lymphocytes decreased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Campylobacter test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Creatinine renal clearance decreased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Culture urine positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hepatic enzyme increased						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Parasite stool test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella test positive						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Fibrous histiocyoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	1/252 (<1%)				
Hypertension						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure inadequately controlled						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Thrombophlebitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75	>999 (>999, >999) /NC	3.6449 (-19.9869, 27.2768) /0.762	>999 (>999, >999) /NC	0.248
Male	5/254 (2%)	5/252 (2%)	0.9920 (0.2836, 3.4693) /0.990	-0.0156 (-2.4411, 2.4099) /0.990	0.9921 (0.2908, 3.3851) /0.990	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				
Testicular cyst						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Benign prostatic hyperplasia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cervical dysplasia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermi a						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Penile burning sensation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile discharge						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Priapism						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Prostatitis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular torsion						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear and labyrinth disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Renal and urinary disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pollakiuria						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Renal colic						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Leukocyturia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ureterolithiasis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
Female	3/ 73 (4%)	1/ 75 (1%)				
Male	2/254 (<1%)	3/252 (1%)				
Blepharitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis allergic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Blepharospasm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cataract						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Diplopia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Eyelid oedema						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Retinal detachment						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Ulcerative keratitis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	4/252 (2%)				
Hypercholesterolaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Obesity						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cachexia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
Female	2/ 73 (3%)	0/ 75				
Male	2/254 (<1%)	5/252 (2%)				
Seasonal allergy						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	1/252 (<1%)				
Food allergy						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	0/252				
Iron deficiency anaemia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neutropenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cardiac disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	4/254 (2%)	4/252 (2%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Tachycardia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Angina pectoris						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial fibrillation						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cardiac aneurysm						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ventricular extrasystoles						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hepatobiliary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Jaundice						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Congenital, familial and genetic disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial septal defect						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Benign familial pemphigus						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	3/ 73 (4%)	6/ 75 (8%)	0.4929 (0.1185, 2.0497) /0.331	-3.8904 (-11.5347, 3.7538) /0.319	0.5137 (0.1334, 1.9774) /0.333	0.792
Male	17/254 (7%)	27/252 (11%)	0.5977 (0.3172, 1.1265) /0.111	-4.0214 (-8.9232, 0.8804) /0.108	0.6247 (0.3493, 1.1171) /0.113	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.245
Male	7/254 (3%)	16/252 (6%)	0.4180 (0.1689, 1.0343) /0.059	-3.5933 (-7.2151, 0.0285) /0.052	0.4341 (0.1817, 1.0370) /0.060	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.264
Male	6/254 (2%)	15/252 (6%)	0.3823 (0.1459, 1.0017) /0.050	-3.5902 (-7.0574, -0.1229) /0.042	0.3969 (0.1565, 1.0064) /0.052	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Pyrexia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Fatigue						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site warmth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Injection site discolouration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	3/254 (1%)	4/252 (2%)				
Pneumonia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Hepatitis E						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epididymitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Anal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erysipelas						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Gastrointestinal disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abdominal pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Haemorrhoidal haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oroantral fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Pain in extremity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Myalgia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Intervertebral disc protrusion						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Osteoarthritis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Osteonecrosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Cerebrovascular accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Depression						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Injury, poisoning and procedural complications						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Investigations

Any Event

Female	0/ 73	1/ 75 (1%)
Male	2/254 (<1%)	0/252

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Transaminases increased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

White blood cell count decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Ear and labyrinth disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Renal and urinary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal colic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eye disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Retinal detachment						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Metabolism and nutrition disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Immune system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Cardiac disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Abortion spontaneous						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	2/252 (<1%)				
Infections and infestations						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Epiglottitis obstructive						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Overdose						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.19

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Sex at Birth - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	88/238 (37%)	100/256 (39%)	0.9152 (0.6361, 1.3167) /0.633	-2.0877 (-10.6511, 6.4757) /0.633	0.9466 (0.7553, 1.1862) /0.633	0.266
Non-White	37/ 89 (42%)	24/ 71 (34%)	1.3934 (0.7291, 2.6630) /0.315	7.7702 (-7.2601, 22.8005) /0.311	1.2299 (0.8177, 1.8498) /0.320	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	122/238 (51%)	125/256 (49%)	1.1022 (0.7743, 1.5689) /0.589	2.4324 (-6.3892, 11.2539) /0.589	1.0498 (0.8802, 1.2522) /0.589	0.446
Non-White	43/ 89 (48%)	28/ 71 (39%)	1.4356 (0.7631, 2.7007) /0.262	8.8780 (-6.5171, 24.2731) /0.258	1.2251 (0.8551, 1.7552) /0.268	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
White	116/238 (49%)	123/256 (48%)	1.0281 (0.7222, 1.4636) /0.878	0.6926 (-8.1268, 9.5121) /0.878	1.0144 (0.8454, 1.2172) /0.878	0.176
Non-White	41/ 89 (46%)	24/ 71 (34%)	1.6727 (0.8780, 3.1870) /0.118	12.2646 (-2.8452, 27.3744) /0.112	1.3628 (0.9176, 2.0241) /0.125	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
White	18/238 (8%)	33/256 (13%)	0.5529 (0.3023, 1.0112) /0.054	-5.3276 (-10.6317, -0.0235) /0.049	0.5867 (0.3397, 1.0134) /0.056	0.781
Non-White	9/ 89 (10%)	14/ 71 (20%)	0.4580 (0.1855, 1.1307) /0.090	-9.6060 (-20.7811, 1.5692) /0.092	0.5128 (0.2358, 1.1156) /0.092	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
White	16/238 (7%)	23/256 (9%)	0.7301 (0.3759, 1.4183) /0.353	-2.2617 (-6.9937, 2.4703) /0.349	0.7483 (0.4053, 1.3815) /0.354	0.391
Non-White	4/ 89 (4%)	2/ 71 (3%)	1.6235 (0.2887, 9.1288) /0.582	1.6775 (-4.0965, 7.4514) /0.569	1.5955 (0.3008, 8.4627) /0.583	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
White	16/238 (7%)	21/256 (8%)	0.8065 (0.4103, 1.5853) /0.533	-1.4804 (-6.1087, 3.1478) /0.531	0.8195 (0.4382, 1.5326) /0.533	0.697
Non-White	3/ 89 (3%)	4/ 71 (6%)	0.5843 (0.1264, 2.7001) /0.491	-2.2630 (-8.8070, 4.2809) /0.498	0.5983 (0.1384, 2.5869) /0.492	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	12/238 (5%)	24/256 (9%)	0.5133 (0.2506, 1.0511) /0.068	-4.3330 (-8.8581, 0.1921) /0.061	0.5378 (0.2752, 1.0511) /0.070	0.400
Non-White	3/ 89 (3%)	2/ 71 (3%)	1.2035 (0.1956, 7.4056) /0.842	0.5539 (-4.8192, 5.9270) /0.840	1.1966 (0.2055, 6.9679) /0.842	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
White	9/238 (4%)	8/256 (3%)	1.2183 (0.4622, 3.2112) /0.690	0.6565 (-2.5708, 3.8838) /0.690	1.2101 (0.4746, 3.0850) /0.690	0.592
Non-White	5/ 89 (6%)	5/ 71 (7%)	0.7857 (0.2183, 2.8283) /0.712	-1.4243 (-9.0601, 6.2115) /0.715	0.7978 (0.2403, 2.6479) /0.712	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue White	2/238 (<1%)	16/256 (6%)	0.1271 (0.0289, 0.5589) /0.006	-5.4097 (-8.5936, -2.2257) /<.001	0.1345 (0.0312, 0.5786) /0.007	0.039
Non-White	4/ 89 (4%)	3/ 71 (4%)	1.0667 (0.2308, 4.9287) /0.934	0.2690 (-6.0888, 6.6269) /0.934	1.0637 (0.2460, 4.5989) /0.934	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
White	4/238 (2%)	11/256 (4%)	0.3807 (0.1196, 1.2125) /0.102	-2.6162 (-5.5890, 0.3566) /0.085	0.3911 (0.1263, 1.2117) /0.104	0.985
Non-White	2/ 89 (2%)	4/ 71 (6%)	0.3851 (0.0685, 2.1655) /0.279	-3.3866 (-9.5709, 2.7977) /0.283	0.3989 (0.0752, 2.1157) /0.280	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
White	8/238 (3%)	10/256 (4%)	0.8557 (0.3319, 2.2057) /0.747	-0.5449 (-3.8427, 2.7529) /0.746	0.8605 (0.3454, 2.1437) /0.747	0.959
Non-White	1/ 89 (1%)	1/ 71 (1%)	0.7955 (0.0489, 12.9447) /0.872	-0.2849 (-3.7932, 3.2235) /0.874	0.7978 (0.0508, 12.5315) /0.872	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia						
White	10/238 (4%)	6/256 (2%)	1.8275 (0.6538, 5.1082) /0.250	1.8579 (-1.2935, 5.0093) /0.248	1.7927 (0.6617, 4.8566) /0.251	0.398
Non-White	1/ 89 (1%)	0/ 71	>999 (>999, >999) /NC	3.3900 (-20.7115, 27.4914) /0.783	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
White	8/238 (3%)	6/256 (2%)	1.4493 (0.4954, 4.2402) /0.498	1.0176 (-1.9282, 3.9634) /0.498	1.4342 (0.5051, 4.0726) /0.498	0.936
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
White	3/238 (1%)	7/256 (3%)	0.4541 (0.1161, 1.7767) /0.257	-1.4739 (-3.9233, 0.9756) /0.238	0.4610 (0.1206, 1.7622) /0.258	0.505
Non-White	1/ 89 (1%)	4/ 71 (6%)	0.1903 (0.0208, 1.7424) /0.142	-4.5102 (-10.3033, 1.2829) /0.127	0.1994 (0.0228, 1.7450) /0.145	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
White	8/238 (3%)	4/256 (2%)	2.1913 (0.6512, 7.3740) /0.205	1.7988 (-0.9491, 4.5468) /0.199	2.1513 (0.6563, 7.0515) /0.206	0.032
Non-White	0/ 89	2/ 71 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0722 (-26.9035, 16.7592) /0.649	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
White	4/238 (2%)	6/256 (2%)	0.7123 (0.1985, 2.5557) /0.603	-0.6631 (-3.1332, 1.8071) /0.599	0.7171 (0.2049, 2.5099) /0.603	0.237
Non-White	1/ 89 (1%)	0/ 71	>999 (>999, >999) /NC	3.3900 (-20.7115, 27.4914) /0.783	>999 (>999, >999) /NC	
Pain						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
White	0/238	7/256 (3%)				
Non-White	0/ 89	1/ 71 (1%)				
Discomfort						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				
Injection site anaesthesia						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chest pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Feeling hot						
White	2/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nodule						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Injection site papule						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vessel puncture site haematoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Chest discomfort						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chronic fatigue syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Gait disturbance						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Induration						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Inflammation						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site rash						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Non-cardiac chest pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oedema peripheral						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Peripheral swelling						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Sluggishness						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Thirst						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Xerosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	84/238 (35%)	102/256 (40%)	0.8235 (0.5716, 1.1864) /0.297	-4.5496 (-13.0835, 3.9843) /0.296	0.8858 (0.7048, 1.1133) /0.298	0.870
Non-White	21/ 89 (24%)	18/ 71 (25%)	0.9093 (0.4405, 1.8771) /0.797	-1.7566 (-15.1807, 11.6675) /0.798	0.9307 (0.5387, 1.6081) /0.797	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	30/238 (13%)	37/256 (14%)	0.8537 (0.5088, 1.4324) /0.549	-1.8481 (-7.8759, 4.1797) /0.548	0.8721 (0.5572, 1.3651) /0.549	0.846
Non-White	5/ 89 (6%)	4/ 71 (6%)	0.9970 (0.2576, 3.8591) /0.997	-0.0158 (-7.2027, 7.1710) /0.997	0.9972 (0.2780, 3.5767) /0.997	

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Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	16/238 (7%)	29/256 (11%)	0.5642 (0.2981, 1.0675) /0.079	-4.6054 (-9.6248, 0.4140) /0.072	0.5935 (0.3308, 1.0645) /0.080	0.745
Non-White	8/ 89 (9%)	9/ 71 (13%)	0.6804 (0.2483, 1.8646) /0.454	-3.6873 (-13.4444, 6.0698) /0.459	0.7091 (0.2883, 1.7439) /0.454	

Note: "Any Event" represents subjects with any AE reported.

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Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
White	7/238 (3%)	14/256 (5%)	0.5238 (0.2077, 1.3210) /0.171	-2.5276 (-6.0440, 0.9888) /0.159	0.5378 (0.2209, 1.3096) /0.172	0.065
Non-White	2/ 89 (2%)	0/ 71	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis White	6/238 (3%)	10/256 (4%)	0.6362 (0.2276, 1.7783) /0.389	-1.3852 (-4.4835, 1.7130) /0.381	0.6454 (0.2382, 1.7484) /0.389	0.710
Non-White	1/ 89 (1%)	2/ 71 (3%)	0.3920 (0.0348, 4.4135) /0.448	-1.6933 (-6.1213, 2.7346) /0.454	0.3989 (0.0369, 4.3103) /0.449	

Note: "Any Event" represents subjects with any AE reported.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis White	4/238 (2%)	6/256 (2%)	0.7123 (0.1985, 2.5557) /0.603	-0.6631 (-3.1332, 1.8071) /0.599	0.7171 (0.2049, 2.5099) /0.603	0.289
Non-White	1/ 89 (1%)	4/ 71 (6%)	0.1903 (0.0208, 1.7424) /0.142	-4.5102 (-10.3033, 1.2829) /0.127	0.1994 (0.0228, 1.7450) /0.145	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
White	6/238 (3%)	5/256 (2%)	1.2983 (0.3910, 4.3111) /0.670	0.5679 (-2.0475, 3.1832) /0.670	1.2908 (0.3992, 4.1739) /0.670	0.028
Non-White	0/ 89	3/ 71 (4%)	<0.0001 (<0.0001, -) />0.999	NC	<0.0001 (<0.0001, -) />0.999	
Gonorrhoea						
White	5/238 (2%)	4/256 (2%)				
Non-White	3/ 89 (3%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza						
White	5/238 (2%)	4/256 (2%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				
Sinusitis						
White	4/238 (2%)	7/256 (3%)	0.6081 (0.1757, 2.1041) /0.432	-1.0537 (-3.6340, 1.5266) /0.423	0.6146 (0.1822, 2.0730) /0.433	0.212
Non-White	1/ 89 (1%)	0/ 71	>999 (>999, >999) /NC	3.3900 (-20.7115, 27.4914) /0.783	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydial infection						
White	4/238 (2%)	4/256 (2%)				
Non-White	2/ 89 (2%)	0/ 71				
Respiratory tract infection						
White	5/238 (2%)	5/256 (2%)	1.0773 (0.3079, 3.7688) /0.907	0.1477 (-2.3409, 2.6363) /0.907	1.0756 (0.3154, 3.6688) /0.907	>0.999
Non-White	0/ 89	0/ 71	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
White	4/238 (2%)	6/256 (2%)	0.7123 (0.1985, 2.5557) /0.603	-0.6631 (-3.1332, 1.8071) /0.599	0.7171 (0.2049, 2.5099) /0.603	>0.999
Non-White	0/ 89	0/ 71	NC	NC	NC	
Rhinitis						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	2/ 71 (3%)				
Urinary tract infection						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	2/ 71 (3%)				
Oral herpes						
White	1/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Viral infection						
White	3/238 (1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
White	1/238 (<1%)	4/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Folliculitis						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Herpes simplex						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Hordeolum						
White	1/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
White	1/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Ear infection						
White	0/238	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Fungal skin infection						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Gingivitis						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Herpes zoster						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Onychomycosis						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Proctitis gonococcal						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Tooth infection						
White	0/238	4/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Furuncle						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Lower respiratory tract infection						
White	0/238	0/256				
Non-White	3/ 89 (3%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Otitis externa						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Secondary syphilis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	2/ 71 (3%)				
Tooth abscess						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	2/ 71 (3%)				
Vaginal infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal chlamydia infection						
White	0/238	0/256				
Non-White	2/ 89 (2%)	0/ 71				
Body tinea						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Helicobacter infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lymphogranuloma venereum						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Mycoplasma genitalium infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Oropharyngeal gonococcal infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Paronychia						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pneumonia						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Postoperative wound infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin infection						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal infection						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tinea infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral pharyngitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Acarodermatitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod infestation						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
 Bronchitis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Candida infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cellulitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chronic sinusitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cutaneous blastomycosis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Cystitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Enteritis infectious						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Enterovirus infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Erythema migrans						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia urinary tract infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
External ear cellulitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastritis viral						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Genital herpes						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes simplex						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gingival abscess						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Groin abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hepatitis E						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Infectious mononucleosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Labyrinthitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Laryngitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Mycoplasma infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Otitis media acute						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Penile infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pericoronitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Peritonsillar abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Pharyngitis bacterial						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis mycoplasmal						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pharyngitis streptococcal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Primary syphilis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis mycoplasmal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pulpitis dental						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Schistosomiasis cutaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Syphilis genital						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea capitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Tinea cruris						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tinea pedis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tracheobronchitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Trichomoniasis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Varicella						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Viral rash						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral rhinitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	42/238 (18%)	54/256 (21%)	0.8016 (0.5118, 1.2553) /0.334	-3.4467 (-10.4061, 3.5127) /0.332	0.8366 (0.5822, 1.2022) /0.335	0.599
Non-White	10/ 89 (11%)	12/ 71 (17%)	0.6224 (0.2519, 1.5376) /0.304	-5.6655 (-16.5759, 5.2450) /0.309	0.6648 (0.3050, 1.4489) /0.304	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	18/238 (8%)	17/256 (7%)	1.1503 (0.5783, 2.2880) /0.690	0.9224 (-3.6149, 5.4597) /0.690	1.1389 (0.6012, 2.1576) /0.690	0.785
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea White	4/238 (2%)	14/256 (5%)	0.2955 (0.0959, 0.9107) /0.034	-3.7881 (-7.0168, -0.5594) /0.021	0.3073 (0.1026, 0.9206) /0.035	0.909
Non-White	1/ 89 (1%)	3/ 71 (4%)	0.2576 (0.0262, 2.5313) /0.245	-3.1018 (-8.2680, 2.0645) /0.239	0.2659 (0.0283, 2.5018) /0.247	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
White	6/238 (3%)	5/256 (2%)	1.2983 (0.3910, 4.3111) /0.670	0.5679 (-2.0475, 3.1832) /0.670	1.2908 (0.3992, 4.1739) /0.670	0.065
Non-White	0/ 89	2/ 71 (3%)	<0.0001 (<0.0001, -) />0.999	-5.0722 (-26.9035, 16.7592) /0.649	<0.0001 (<0.0001, -) />0.999	
Abdominal pain						
White	4/238 (2%)	5/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
White	1/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Constipation						
White	0/238	6/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				
Abdominal distension						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Toothache						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Vomiting						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Abdominal pain upper						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroesophageal reflux disease						
White	3/238 (1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Abdominal discomfort						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Anogenital dysplasia						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Flatulence						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Dry mouth						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gingival pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Inguinal hernia						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Irritable bowel syndrome						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Noninfective gingivitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rectal discharge						
White	0/238	0/256				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Abdominal hernia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal tenderness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anal fistula						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anal pruritus						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angular cheilitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cheilitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Dental caries						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Food poisoning						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Gastric disorder						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gingival hypertrophy						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Haematemesis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematochezia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hiatus hernia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hypertrophic anal papilla						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Large intestine polyp						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Oesophagitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pancreatitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Perianal erythema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Proctalgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tooth disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
White	32/238 (13%)	48/256 (19%)	0.6731 (0.4136, 1.0955) /0.111	-5.3046 (-11.7578, 1.1486) /0.107	0.7171 (0.4754, 1.0816) /0.113	0.216
Non-White	9/ 89 (10%)	5/ 71 (7%)	1.4850 (0.4746, 4.6468) /0.497	3.0701 (-5.5701, 11.7103) /0.486	1.4360 (0.5036, 4.0944) /0.499	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	10/238 (4%)	14/256 (5%)	0.7581 (0.3301, 1.7411) /0.514	-1.2671 (-5.0426, 2.5084) /0.511	0.7683 (0.3480, 1.6964) /0.514	0.967
Non-White	3/ 89 (3%)	3/ 71 (4%)	0.7907 (0.1547, 4.0421) /0.778	-0.8546 (-6.8507, 5.1416) /0.780	0.7978 (0.1660, 3.8331) /0.778	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	6/238 (3%)	10/256 (4%)	0.6362 (0.2276, 1.7783) /0.389	-1.3852 (-4.4835, 1.7130) /0.381	0.6454 (0.2382, 1.7484) /0.389	0.150
Non-White	4/ 89 (4%)	1/ 71 (1%)	3.2941 (0.3599, 30.1490) /0.291	3.0859 (-2.0170, 8.1889) /0.236	3.1910 (0.3647, 27.9198) /0.294	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
White	6/238 (3%)	8/256 (3%)	0.8017 (0.2740, 2.3456) /0.687	-0.6040 (-3.5210, 2.3131) /0.685	0.8067 (0.2841, 2.2908) /0.687	0.587
Non-White	1/ 89 (1%)	2/ 71 (3%)	0.3920 (0.0348, 4.4135) /0.448	-1.6933 (-6.1213, 2.7346) /0.454	0.3989 (0.0369, 4.3103) /0.449	
Myalgia						
White	5/238 (2%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
White	2/238 (<1%)	4/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Muscle contracture						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Muscle spasms						
White	0/238	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Neck pain						
White	3/238 (1%)	0/256				
Non-White	0/ 89	0/ 71				
Tendonitis						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bursitis						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Intervertebral disc protrusion						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Arthritis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Arthropathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical spinal stenosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Exostosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Femoroacetabular impingement						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Flank pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint range of motion decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Joint stiffness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint swelling						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Limb discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Muscular weakness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Musculoskeletal stiffness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Osteopenia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Rotator cuff syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Scoliosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Spinal osteoarthritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Synovial cyst						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Temporomandibular joint syndrome						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon disorder						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Tenosynovitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Trigger finger						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	27/238 (11%)	37/256 (14%)	0.7574 (0.4454, 1.2879) /0.305	-3.1086 (-9.0066, 2.7894) /0.302	0.7849 (0.4937, 1.2479) /0.306	0.971
Non-White	12/ 89 (13%)	12/ 71 (17%)	0.7662 (0.3213, 1.8272) /0.548	-3.4183 (-14.6583, 7.8218) /0.551	0.7978 (0.3818, 1.6668) /0.548	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus						
White	4/238 (2%)	3/256 (1%)				
Non-White	4/ 89 (4%)	4/ 71 (6%)				
Rash						
White	4/238 (2%)	7/256 (3%)	0.6081 (0.1757, 2.1041) /0.432	-1.0537 (-3.6340, 1.5266) /0.423	0.6146 (0.1822, 2.0730) /0.433	0.823
Non-White	2/ 89 (2%)	2/ 71 (3%)	0.7931 (0.1089, 5.7746) /0.819	-0.5697 (-5.4985, 4.3591) /0.821	0.7978 (0.1152, 5.5236) /0.819	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema						
White	3/238 (1%)	4/256 (2%)				
Non-White	0/ 89	3/ 71 (4%)				
Alopecia						
White	5/238 (2%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Acne						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin lesion						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Dermatitis						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Seborrhoeic dermatitis						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
White	2/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Dermal cyst						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Dermatitis contact						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dry skin						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hyperhidrosis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rash erythematous						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin exfoliation						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Urticaria						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Androgenetic alopecia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chloasma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cold sweat						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Drug eruption						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Ecchymosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema asteatotic						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Erythema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Intertrigo						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Keratosis pilaris						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Macule						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Miliaria						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail bed inflammation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Penile ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Petechiae						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pigmentation disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pityriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pityriasis rosea						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus generalised						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Psoriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Purpura						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash morbilliform						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin discolouration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin hypertrophy						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Skin irritation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Solar dermatitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	24/238 (10%)	33/256 (13%)	0.7579 (0.4337, 1.3244) /0.330	-2.8066 (-8.4177, 2.8045) /0.327	0.7823 (0.4767, 1.2837) /0.331	0.591
Non-White	8/ 89 (9%)	6/ 71 (8%)	1.0700 (0.3534, 3.2391) /0.905	0.5381 (-8.2465, 9.3226) /0.904	1.0637 (0.3868, 2.9248) /0.905	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	10/238 (4%)	12/256 (5%)	0.8918 (0.3780, 2.1041) /0.794	-0.4858 (-4.1191, 3.1475) /0.793	0.8964 (0.3946, 2.0361) /0.794	0.211
Non-White	3/ 89 (3%)	7/ 71 (10%)	0.3189 (0.0794, 1.2813) /0.107	-6.4884 (-14.3714, 1.3947) /0.107	0.3419 (0.0917, 1.2748) /0.110	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal pain						
White	4/238 (2%)	8/256 (3%)	0.5299 (0.1575, 1.7832) /0.305	-1.4443 (-4.1294, 1.2408) /0.292	0.5378 (0.1641, 1.7629) /0.306	0.219
Non-White	3/ 89 (3%)	1/ 71 (1%)	2.4418 (0.2485, 23.9941) /0.444	1.9623 (-2.6822, 6.6069) /0.408	2.3933 (0.2544, 22.5162) /0.445	
Sinus congestion						
White	2/238 (<1%)	5/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
White	3/238 (1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Rhinitis allergic						
White	3/238 (1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Epistaxis						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthma						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Catarrh						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dyspnoea						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oropharyngeal discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Productive cough						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Rales						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Sleep apnoea syndrome						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Bronchospasm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry throat						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haemoptysis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Interstitial lung disease						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal oedema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nasal septum deviation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Painful respiration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pleuritic pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Respiratory disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	27/238 (11%)	30/256 (12%)	0.9640 (0.5546, 1.6754) /0.897	-0.3742 (-6.0096, 5.2612) /0.896	0.9681 (0.5936, 1.5787) /0.897	0.572
Non-White	7/ 89 (8%)	4/ 71 (6%)	1.4299 (0.4015, 5.0924) /0.581	2.2314 (-5.5173, 9.9801) /0.572	1.3961 (0.4255, 4.5808) /0.582	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache						
White	12/238 (5%)	16/256 (6%)	0.7965 (0.3687, 1.7205) /0.563	-1.2080 (-5.2725, 2.8565) /0.560	0.8067 (0.3898, 1.6696) /0.563	0.068
Non-White	6/ 89 (7%)	1/ 71 (1%)	5.0602 (0.5949, 43.0416) /0.138	5.3331 (-0.5533, 11.2195) /0.076	4.7865 (0.5897, 38.8500) /0.143	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
White	9/238 (4%)	5/256 (2%)	1.9729 (0.6516, 5.9734) /0.229	1.8284 (-1.1290, 4.7858) /0.226	1.9361 (0.6582, 5.6949) /0.230	0.220
Non-White	1/ 89 (1%)	2/ 71 (3%)	0.3920 (0.0348, 4.4135) /0.448	-1.6933 (-6.1213, 2.7346) /0.454	0.3989 (0.0369, 4.3103) /0.449	
Paraesthesia						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Presyncope						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Somnolence						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lethargy						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Amnesia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Burning sensation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cervical radiculopathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dysarthria						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Head discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hyperaesthesia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersomnia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hypoaesthesia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Muscle contractions involuntary						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Polyneuropathy						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sciatica						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tension headache						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	14/238 (6%)	23/256 (9%)	0.6332 (0.3178, 1.2614) /0.194	-3.1020 (-7.7071, 1.5030) /0.187	0.6547 (0.3451, 1.2423) /0.195	0.594
Non-White	6/ 89 (7%)	10/ 71 (14%)	0.4410 (0.1521, 1.2788) /0.132	-7.3429 (-16.9662, 2.2804) /0.135	0.4787 (0.1827, 1.2537) /0.134	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
White	3/238 (1%)	7/256 (3%)	0.4541 (0.1161, 1.7767) /0.257	-1.4739 (-3.9233, 0.9756) /0.238	0.4610 (0.1206, 1.7622) /0.258	0.560
Non-White	3/ 89 (3%)	9/ 71 (13%)	0.2403 (0.0625, 0.9240) /0.038	-9.3053 (-17.9046, -0.7059) /0.034	0.2659 (0.0748, 0.9458) /0.041	
Anxiety						
White	3/238 (1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abnormal dreams						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Depressed mood						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nightmare						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Sleep disorder						
White	0/238	4/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Drug abuse						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Irritability						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Adjustment disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Adjustment disorder with mixed anxiety and depressed mood						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Agoraphobia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Emotional distress						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Loss of libido						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Mood swings						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Nervousness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic stress disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Stress						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury, poisoning and procedural complications						
Any Event						
White	13/238 (5%)	29/256 (11%)	0.4523 (0.2292, 0.8924) /0.022	-5.8659 (-10.7041, -1.0278) /0.017	0.4822 (0.2568, 0.9053) /0.023	0.802
Non-White	3/ 89 (3%)	6/ 71 (8%)	0.3779 (0.0911, 1.5679) /0.180	-5.0799 (-12.5577, 2.3979) /0.183	0.3989 (0.1034, 1.5392) /0.182	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Arthropod bite						
White	2/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				
Limb injury						
White	3/238 (1%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Contusion						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Exposure to communicable disease						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
White	0/238	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Skin laceration						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Animal bite						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Arthropod sting						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Bone contusion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Concussion						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Epicondylitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Fall						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Heat stroke						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection related reaction						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injury corneal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lip injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nail injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Procedural pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Road traffic accident						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Sunburn						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Traumatic haematoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Ulna fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
White	9/238 (4%)	15/256 (6%)	0.6314 (0.2710, 1.4714) /0.287	-2.0779 (-5.8395, 1.6838) /0.279	0.6454 (0.2879, 1.4469) /0.288	0.774
Non-White	5/ 89 (6%)	5/ 71 (7%)	0.7857 (0.2183, 2.8283) /0.712	-1.4243 (-9.0601, 6.2115) /0.715	0.7978 (0.2403, 2.6479) /0.712	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
White	1/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				
Blood pressure increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Blood creatine phosphokinase increased						
White	0/238	1/256 (<1%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood cholesterol increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood glucose increased						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Low density lipoprotein increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Aspartate aminotransferase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood bilirubin unconjugated increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood creatinine increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Blood triglycerides increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chlamydia test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Escherichia test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematocrit increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Haemoglobin increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intraocular pressure increased						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Vitamin D decreased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	7/238 (3%)	15/256 (6%)	0.4869 (0.1950, 1.2157) /0.123	-2.9182 (-6.5077, 0.6713) /0.111	0.5020 (0.2083, 1.2097) /0.125	0.175
Non-White	1/ 89 (1%)	0/ 71	>999 (>999, >999) /NC	3.3900 (-20.7115, 27.4914) /0.783	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	2/238 (<1%)	6/256 (2%)				
Non-White	1/ 89 (1%)	0/ 71				
Skin papilloma						
White	0/238	6/256 (2%)				
Non-White	0/ 89	0/ 71				
Acrochordon						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Basal cell carcinoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Fibroma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Fibrous histiocytoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lipoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Lipoma of breast						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethral papilloma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Uterine leiomyoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	10/238 (4%)	9/256 (4%)	1.2037 (0.4805, 3.0155) /0.692	0.6861 (-2.7179, 4.0900) /0.693	1.1951 (0.4942, 2.8903) /0.692	0.382
Non-White	1/ 89 (1%)	2/ 71 (3%)	0.3920 (0.0348, 4.4135) /0.448	-1.6933 (-6.1213, 2.7346) /0.454	0.3989 (0.0369, 4.3103) /0.449	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
White	7/238 (3%)	3/256 (1%)	2.5556 (0.6532, 9.9990) /0.178	1.7693 (-0.7497, 4.2883) /0.169	2.5098 (0.6566, 9.5941) /0.179	0.171
Non-White	1/ 89 (1%)	2/ 71 (3%)	0.3920 (0.0348, 4.4135) /0.448	-1.6933 (-6.1213, 2.7346) /0.454	0.3989 (0.0369, 4.3103) /0.449	
Flushing						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematoma						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Peripheral venous disease						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hot flush						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypotension						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Peripheral coldness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Varicose vein						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	9/238 (4%)	9/256 (4%)	1.0786 (0.4208, 2.7647) /0.875	0.2659 (-3.0451, 3.5769) /0.875	1.0756 (0.4343, 2.6640) /0.875	0.840
Non-White	1/ 89 (1%)	1/ 71 (1%)	0.7955 (0.0489, 12.9447) /0.872	-0.2849 (-3.7932, 3.2235) /0.874	0.7978 (0.0508, 12.5315) /0.872	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Erectile dysfunction						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Prostatomegaly						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrophic vulvovaginitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Balanoposthitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast cyst						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Breast pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Genital erythema						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Penile pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Testicular cyst						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular mass						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Testicular pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testis discomfort						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Uterine polyp						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vaginal discharge						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear and labyrinth disorders						
Any Event						
White	6/238 (3%)	7/256 (3%)	0.9200 (0.3047, 2.7775) /0.882	-0.2134 (-3.0343, 2.6075) /0.882	0.9220 (0.3143, 2.7042) /0.882	0.599
Non-White	2/ 89 (2%)	3/ 71 (4%)	0.5211 (0.0847, 3.2067) /0.482	-1.9782 (-7.5797, 3.6233) /0.489	0.5318 (0.0913, 3.0968) /0.482	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinnitus						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Vertigo						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cerumen impaction						
White	1/238 (<1%)	0/256				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Excessive cerumen production						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deafness neurosensory						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ear pain						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Hypoacusis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
White	2/238 (<1%)	10/256 (4%)	0.2085 (0.0452, 0.9615) /0.044	-3.0659 (-5.7074, -0.4244) /0.023	0.2151 (0.0476, 0.9718) /0.046	0.291
Non-White	2/ 89 (2%)	2/ 71 (3%)	0.7931 (0.1089, 5.7746) /0.819	-0.5697 (-5.4985, 4.3591) /0.821	0.7978 (0.1152, 5.5236) /0.819	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysuria						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Micturition urgency						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nocturia						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematuria						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Micturition disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nephrolithiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nephropathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pollakiuria						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Urethral disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract disorder						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Eye disorders						
Any Event						
White	1/238 (<1%)	8/256 (3%)				
Non-White	1/ 89 (1%)	3/ 71 (4%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Conjunctivitis allergic						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dry eye						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eye pain						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Eyelid cyst						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Glaucoma						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Mydriasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ocular hyperaemia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pterygium						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vision blurred						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Vitreous floaters						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	2/238 (<1%)	4/256 (2%)				
Non-White	3/ 89 (3%)	4/ 71 (6%)				
Decreased appetite						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Vitamin D deficiency						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gluten sensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gout						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hyperglycaemia ^a						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Hypokalaemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Obesity						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Immune system disorders						
Any Event						
White	4/238 (2%)	3/256 (1%)				
Non-White	3/ 89 (3%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Seasonal allergy						
White	3/238 (1%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				
Hypersensitivity						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anaemia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Lymph node pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lymphadenopathy						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Endocrine disorders						
Any Event						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Goitre						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Palpitations						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tachycardia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hepatobiliary disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hepatomegaly						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Menopause						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Stress at work						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Congenital, familial and genetic disorders						
Any Event						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type V hyperlipidaemia						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	118/238 (50%)	115/256 (45%)	1.2057 (0.8463, 1.7175) /0.300	4.6580 (-4.1441, 13.4600) /0.300	1.1037 (0.9158, 1.3301) /0.300	0.166
Non-White	38/ 89 (43%)	36/ 71 (51%)	0.7244 (0.3870, 1.3558) /0.313	-8.0076 (-23.5266, 7.5114) /0.312	0.8421 (0.6039, 1.1742) /0.311	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	79/238 (33%)	79/256 (31%)	1.1132 (0.7626, 1.6251) /0.578	2.3339 (-5.9007, 10.5685) /0.579	1.0756 (0.8318, 1.3910) /0.578	0.477
Non-White	28/ 89 (31%)	25/ 71 (35%)	0.8446 (0.4360, 1.6363) /0.617	-3.7506 (-18.4645, 10.9634) /0.617	0.8935 (0.5754, 1.3873) /0.616	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
White	72/238 (30%)	69/256 (27%)	1.1755 (0.7952, 1.7375) /0.417	3.2990 (-4.6760, 11.2740) /0.417	1.1224 (0.8491, 1.4837) /0.417	0.511
Non-White	27/ 89 (30%)	23/ 71 (32%)	0.9088 (0.4642, 1.7792) /0.780	-2.0573 (-16.5387, 12.4241) /0.781	0.9365 (0.5909, 1.4842) /0.780	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
White	2/238 (<1%)	8/256 (3%)	0.2627 (0.0552, 1.2498) /0.093	-2.2847 (-4.7111, 0.1418) /0.065	0.2689 (0.0577, 1.2536) /0.094	0.503
Non-White	1/ 89 (1%)	7/ 71 (10%)	0.1039 (0.0125, 0.8655) /0.036	-8.7356 (-16.0074, -1.4638) /0.019	0.1140 (0.0144, 0.9049) /0.040	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
White	4/238 (2%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Injection site induration						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	4/238 (2%)	7/256 (3%)	0.6081 (0.1757, 2.1041) /0.432	-1.0537 (-3.6340, 1.5266) /0.423	0.6146 (0.1822, 2.0730) /0.433	0.865
Non-White	1/ 89 (1%)	1/ 71 (1%)	0.7955 (0.0489, 12.9447) /0.872	-0.2849 (-3.7932, 3.2235) /0.874	0.7978 (0.0508, 12.5315) /0.872	
Injection site swelling						
White	3/238 (1%)	2/256 (<1%)				
Non-White	5/ 89 (6%)	4/ 71 (6%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
White	0/238	2/256 (<1%)				
Non-White	2/ 89 (2%)	2/ 71 (3%)				
Injection site pruritus						
White	0/238	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Injection site erythema						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthenia						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Chills						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Influenza like illness						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Malaise						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site haematoma						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Discomfort						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Injection site reaction						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Chest pain						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Nodule						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Vessel puncture site haematoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest discomfort						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Gait disturbance						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Non-cardiac chest pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Peripheral swelling						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discharge						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Injection site fibrosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site hypersensitivity						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site necrosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	46/238 (19%)	57/256 (22%)	0.8364 (0.5408, 1.2937) /0.422	-2.9379 (-10.0890, 4.2132) /0.421	0.8681 (0.6141, 1.2270) /0.423	0.920
Non-White	20/ 89 (22%)	19/ 71 (27%)	0.7933 (0.3847, 1.6359) /0.531	-4.2887 (-17.7512, 9.1739) /0.532	0.8397 (0.4869, 1.4482) /0.530	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
White	11/238 (5%)	8/256 (3%)	1.5022 (0.5937, 3.8010) /0.390	1.4968 (-1.9175, 4.9112) /0.390	1.4790 (0.6053, 3.6140) /0.391	0.200
Non-White	2/ 89 (2%)	0/ 71	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
White	5/238 (2%)	7/256 (3%)	0.7633 (0.2389, 2.4385) /0.649	-0.6335 (-3.3373, 2.0703) /0.646	0.7683 (0.2472, 2.3879) /0.649	0.747
Non-White	6/ 89 (7%)	8/ 71 (11%)	0.5693 (0.1880, 1.7240) /0.319	-4.5260 (-13.5389, 4.4868) /0.325	0.5983 (0.2176, 1.6452) /0.320	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
White	2/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	3/ 71 (4%)				
Pharyngitis						
White	2/238 (<1%)	6/256 (2%)				
Non-White	2/ 89 (2%)	0/ 71				
Syphilis						
White	2/238 (<1%)	5/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis						
White	5/238 (2%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				
Gonorrhoea						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Influenza						
White	2/238 (<1%)	3/256 (1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinusitis						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chlamydial infection						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory tract infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Respiratory tract infection viral						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Conjunctivitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Urinary tract infection						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Oral herpes						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Viral infection						
White	1/238 (<1%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral upper respiratory tract infection						
White	0/238	0/256				
Non-White	0/ 89	2/ 71 (3%)				
Folliculitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tonsillitis						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Tinea versicolour						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ear infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gastroenteritis viral						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Herpes zoster						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
White	2/238 (<1%)	6/256 (2%)				
Non-White	0/ 89	0/ 71				
Furuncle						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Tooth abscess						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis gonococcal						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anal chlamydia infection						
White	2/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Mycoplasma genitalium infection						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Oral candidiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Oropharyngeal gonococcal infection						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pneumonia						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Viral pharyngitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cellulitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cystitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Enteritis infectious						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Genital herpes						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pharyngeal chlamydia infection						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pharyngitis streptococcal						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pharyngotonsillitis						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pulpitis dental						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Staphylococcal skin infection						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Tracheitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Varicella						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Urethritis chlamydial						
White	0/238	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Shigella infection						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess limb						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Asymptomatic bacteriuria						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Bacterial diarrhoea						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bacterial rhinitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
 Bacterial vaginosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chest wall abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Dermatophytosis of nail						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Device related infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Diarrhoea infectious						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear infection bacterial						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Enterobiasis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Epididymitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Escherichia infection						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Gastroenteritis						
Escherichia coli						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital candidiasis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Genitourinary tract infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Lice infestation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Oesophageal candidiasis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ophthalmic herpes zoster						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Perirectal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis chlamydial						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pulmonary tuberculosis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Sialoadenitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin bacterial infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Subcutaneous abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	12/238 (5%)	24/256 (9%)	0.5133 (0.2506, 1.0511) /0.068	-4.3330 (-8.8581, 0.1921) /0.061	0.5378 (0.2752, 1.0511) /0.070	0.120
Non-White	5/ 89 (6%)	2/ 71 (3%)	2.0536 (0.3864, 10.9139) /0.399	2.8011 (-3.3388, 8.9409) /0.371	1.9944 (0.3987, 9.9764) /0.401	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
White	4/238 (2%)	5/256 (2%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Nausea						
White	1/238 (<1%)	3/256 (1%)				
Non-White	2/ 89 (2%)	0/ 71				
Dyspepsia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Haemorrhoids						
White	0/238	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Constipation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Toothache						
White	1/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Vomiting						
White	2/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain upper						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gastrooesophageal reflux disease						
White	0/238	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Anogenital dysplasia						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gastritis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Anal fistula						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Colitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal fissure						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Crohn's disease						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gingival ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glossitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haemorrhoids thrombosed						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Intestinal polyp						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Periodontal disease						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Proctitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tongue ulceration						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	15/238 (6%)	16/256 (6%)	1.0090 (0.4874, 2.0887) /0.981	0.0525 (-4.2281, 4.3332) /0.981	1.0084 (0.5099, 1.9943) /0.981	0.386
Non-White	5/ 89 (6%)	7/ 71 (10%)	0.5442 (0.1651, 1.7939) /0.317	-4.2412 (-12.6656, 4.1832) /0.324	0.5698 (0.1888, 1.7195) /0.318	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
White	3/238 (1%)	2/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Arthralgia						
White	5/238 (2%)	3/256 (1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Pain in extremity						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Musculoskeletal pain						
White	5/238 (2%)	0/256				
Non-White	0/ 89	0/ 71				
Muscle contracture						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle spasms						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Musculoskeletal chest pain						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Neck pain						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendonitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Exostosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Limb discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Rotator cuff syndrome						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Synovial cyst						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Groin pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pain in jaw						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periarthritis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Plantar fasciitis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	9/238 (4%)	11/256 (4%)	0.8753 (0.3562, 2.1512) /0.772	-0.5154 (-3.9857, 2.9550) /0.771	0.8801 (0.3713, 2.0861) /0.772	0.686
Non-White	6/ 89 (7%)	4/ 71 (6%)	1.2108 (0.3282, 4.4673) /0.774	1.1078 (-6.3689, 8.5845) /0.772	1.1966 (0.3511, 4.0780) /0.774	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Rash						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Eczema						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alopecia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Skin lesion						
White	3/238 (1%)	0/256				
Non-White	0/ 89	0/ 71				
Dermatitis						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Dermal cyst						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Dermatitis contact						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hyperhidrosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Urticaria						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Skin fissures						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Granuloma annulare						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hand dermatitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lichen sclerosus						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pain of skin						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Rash pruritic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash vesicular						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin swelling						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	4/238 (2%)	11/256 (4%)	0.3807 (0.1196, 1.2125) /0.102	-2.6162 (-5.5890, 0.3566) /0.085	0.3911 (0.1263, 1.2117) /0.104	0.653
Non-White	3/ 89 (3%)	4/ 71 (6%)	0.5843 (0.1264, 2.7001) /0.491	-2.2630 (-8.8070, 4.2809) /0.498	0.5983 (0.1384, 2.5869) /0.492	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
White	0/238	2/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				
Oropharyngeal pain						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Sinus congestion						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nasal congestion						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Rhinitis allergic						
White	1/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	1/ 71 (1%)				
Epistaxis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthma						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Dyspnoea						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Productive cough						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Haemoptysis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Nasal discomfort						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Snoring						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
White	6/238 (3%)	11/256 (4%)	0.5760 (0.2096, 1.5828) /0.285	-1.7759 (-4.9598, 1.4080) /0.274	0.5867 (0.2204, 1.5616) /0.286	0.871
Non-White	5/ 89 (6%)	6/ 71 (8%)	0.6448 (0.1884, 2.2066) /0.485	-2.8327 (-10.8792, 5.2137) /0.490	0.6648 (0.2115, 2.0893) /0.485	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Headache						
White	3/238 (1%)	6/256 (2%)				
Non-White	1/ 89 (1%)	4/ 71 (6%)				
Dizziness						
White	0/238	2/256 (<1%)				
Non-White	2/ 89 (2%)	1/ 71 (1%)				
Presyncope						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Head discomfort						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Hypoaesthesia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Sciatica						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Syncope						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Cerebral infarction						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Hypertonia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Neuropathy peripheral						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Radiculopathy						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
White	14/238 (6%)	6/256 (2%)	2.6042 (0.9840, 6.8918) /0.054	3.5386 (0.0214, 7.0558) /0.049	2.5098 (0.9805, 6.4247) /0.055	0.049
Non-White	1/ 89 (1%)	3/ 71 (4%)	0.2576 (0.0262, 2.5313) /0.245	-3.1018 (-8.2680, 2.0645) /0.239	0.2659 (0.0283, 2.5018) /0.247	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
White	5/238 (2%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Anxiety						
White	5/238 (2%)	3/256 (1%)				
Non-White	1/ 89 (1%)	0/ 71				
Abnormal dreams						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Depression						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Panic attack						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Adjustment disorder with depressed mood						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Restlessness						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	12/238 (5%)	19/256 (7%)	0.6623 (0.3143, 1.3956) /0.279	-2.3799 (-6.6270, 1.8673) /0.272	0.6793 (0.3371, 1.3692) /0.280	0.250
Non-White	1/ 89 (1%)	4/ 71 (6%)	0.1903 (0.0208, 1.7424) /0.142	-4.5102 (-10.3033, 1.2829) /0.127	0.1994 (0.0228, 1.7450) /0.145	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Limb injury						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Contusion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ligament sprain						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Exposure to communicable disease						
White	2/238 (<1%)	3/256 (1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin laceration						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Skin abrasion						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Heat stroke						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Road traffic accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vaccination complication						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Rib fracture						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Joint injury						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Meniscus injury						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Wrist fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Burns second degree						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chemical burns of eye						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Corneal abrasion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibula fracture						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Head injury						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Joint dislocation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scapula fracture						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Investigations

Any Event

White	2/238 (<1%)	7/256 (3%)
Non-White	0/ 89	2/ 71 (3%)

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Alanine aminotransferase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood creatine phosphokinase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Weight increased						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood cholesterol increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Lipase increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
CD4 lymphocytes decreased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

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Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Campylobacter test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Creatinine renal clearance decreased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Culture urine positive						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Hepatic enzyme increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Parasite stool test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella test positive						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Fibrous histiocytoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Hypertension						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood pressure inadequately controlled						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Thrombophlebitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	6/238 (3%)	3/256 (1%)				
Non-White	0/ 89	2/ 71 (3%)				
Erectile dysfunction						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testicular cyst						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Benign prostatic hyperplasia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical dysplasia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Haematospermi a						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile burning sensation						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Penile discharge						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Prostatitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Testicular torsion						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Tinnitus						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Dysuria						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Renal colic						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Leukocyturia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureterolithiasis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Eye disorders						
Any Event						
White	4/238 (2%)	4/256 (2%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Conjunctivitis allergic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blepharospasm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cataract						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Chalazion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Diplopia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid oedema						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Retinal detachment						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Ulcerative keratitis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Metabolism and nutrition disorders						
Any Event						
White	1/238 (<1%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				
Hypercholesterolaemia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vitamin D deficiency						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Obesity						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Type 2 diabetes mellitus						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cachexia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
White	4/238 (2%)	5/256 (2%)				
Non-White	0/ 89	0/ 71				
Seasonal allergy						
White	1/238 (<1%)	2/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Food allergy						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Iron deficiency anaemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neutropenia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cardiac disorders						
Any Event						
White	4/238 (2%)	4/256 (2%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Tachycardia						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Angina pectoris						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial fibrillation						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cardiac aneurysm						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ventricular extrasystoles						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hepatobiliary disorders						
Any Event						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Jaundice						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Congenital, familial and genetic disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Atrial septal defect						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Benign familial pemphigus						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	13/238 (5%)	28/256 (11%)	0.4705 (0.2376, 0.9315) /0.031	-5.4753 (-10.2661, -0.6845) /0.025	0.4994 (0.2650, 0.9411) /0.032	0.210
Non-White	7/ 89 (8%)	5/ 71 (7%)	1.1268 (0.3419, 3.7134) /0.844	0.8229 (-7.3439, 8.9897) /0.843	1.1169 (0.3701, 3.3702) /0.845	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	5/238 (2%)	17/256 (7%)	0.3017 (0.1095, 0.8311) /0.020	-4.5398 (-8.0926, -0.9869) /0.012	0.3164 (0.1186, 0.8441) /0.022	0.201
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	4/238 (2%)	16/256 (6%)	0.2564 (0.0845, 0.7783) /0.016	-4.5693 (-7.9545, -1.1841) /0.008	0.2689 (0.0912, 0.7929) /0.017	0.165
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	
Injection site discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site swelling						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Fatigue						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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PPD

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Chest pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discolouration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Infections and infestations						
Any Event						
White	2/238 (<1%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Diverticulitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hepatitis E						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Epididymitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Acute hepatitis B						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Erysipelas						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Abdominal pain						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Oroantral fistula						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	3/238 (1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Arthralgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Myalgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Muscle spasms						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Rotator cuff syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Costochondritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Osteonecrosis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Sleep apnoea syndrome						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Cerebrovascular accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injury, poisoning and procedural complications						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Investigations

Any Event

White	1/238 (<1%)	1/256 (<1%)
Non-White	1/ 89 (1%)	0/ 71

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body temperature increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Transaminases increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

White blood cell count decreased						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Ear and labyrinth disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Renal and urinary disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Eye disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Retinal detachment						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Metabolism and nutrition disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolaemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Immune system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood and lymphatic system disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cardiac disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Abortion spontaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				
Infections and infestations						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Epiglottitis obstructive						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Overdose						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.20

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Race - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Glioblastoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment.

NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

PPD

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	37/118 (31%)	49/135 (36%)	0.8017 (0.4749, 1.3536) /0.408	-4.9404 (-16.5965, 6.7158) /0.406	0.8639 (0.6099, 1.2237) /0.410	0.532
Europe	72/165 (44%)	64/155 (41%)	1.1008 (0.7063, 1.7156) /0.671	2.3460 (-8.4863, 13.1784) /0.671	1.0568 (0.8185, 1.3645) /0.672	
Rest of World	16/ 44 (36%)	11/ 37 (30%)	1.3506 (0.5302, 3.4405) /0.529	6.6339 (-13.8338, 27.1017) /0.525	1.2231 (0.6508, 2.2989) /0.532	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	50/118 (42%)	56/135 (41%)	1.0373 (0.6288, 1.7111) /0.886	0.8914 (-11.2974, 13.0802) /0.886	1.0215 (0.7639, 1.3659) /0.886	0.483
Europe	98/165 (59%)	80/155 (52%)	1.3713 (0.8810, 2.1344) /0.162	7.7810 (-3.0838, 18.6458) /0.160	1.1508 (0.9442, 1.4025) /0.164	
Rest of World	17/ 44 (39%)	17/ 37 (46%)	0.7407 (0.3052, 1.7979) /0.507	-7.3096 (-28.8698, 14.2506) /0.506	0.8409 (0.5046, 1.4013) /0.506	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	47/118 (40%)	48/135 (36%)	1.1998 (0.7205, 1.9979) /0.484	4.2750 (-7.6926, 16.2425) /0.484	1.1202 (0.8156, 1.5387) /0.483	0.771
Europe	93/165 (56%)	83/155 (54%)	1.1205 (0.7211, 1.7412) /0.613	2.8152 (-8.0892, 13.7197) /0.613	1.0526 (0.8628, 1.2841) /0.613	
Rest of World	17/ 44 (39%)	16/ 37 (43%)	0.8264 (0.3395, 2.0114) /0.674	-4.6069 (-26.0966, 16.8829) /0.674	0.8935 (0.5289, 1.5094) /0.674	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	16/118 (14%)	28/135 (21%)	0.5994 (0.3063, 1.1732) /0.135	-7.1814 (-16.3974, 2.0346) /0.127	0.6538 (0.3725, 1.1472) /0.139	0.365
Europe	10/165 (6%)	14/155 (9%)	0.6498 (0.2797, 1.5096) /0.316	-2.9717 (-8.7698, 2.8265) /0.315	0.6710 (0.3072, 1.4657) /0.317	
Rest of World	1/ 44 (2%)	5/ 37 (14%)	0.1488 (0.0166, 1.3369) /0.089	-11.2408 (-23.1039, 0.6223) /0.063	0.1682 (0.0206, 1.3762) /0.096	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	7/118 (6%)	12/135 (9%)	0.6464 (0.2458, 1.6997) /0.376	-2.9567 (-9.3763, 3.4630) /0.367	0.6674 (0.2717, 1.6395) /0.378	0.845
Europe	13/165 (8%)	13/155 (8%)	0.9342 (0.4189, 2.0834) /0.868	-0.5083 (-6.5034, 5.4867) /0.868	0.9394 (0.4496, 1.9627) /0.868	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	6/118 (5%)	7/135 (5%)	0.9796 (0.3198, 3.0009) /0.971	-0.1004 (-5.5503, 5.3494) /0.971	0.9806 (0.3390, 2.8364) /0.971	0.058
Europe	13/165 (8%)	14/155 (9%)	0.8614 (0.3913, 1.8959) /0.711	-1.1535 (-7.2577, 4.9507) /0.711	0.8723 (0.4236, 1.7963) /0.711	
Rest of World	0/ 44	4/ 37 (11%)	<0.0001 (<0.0001, -) />0.999	-12.7133 (-44.4176, 18.9910) /0.432	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia North America	3/118 (3%)	6/135 (4%)	0.5609 (0.1371, 2.2939) /0.421	-1.9021 (-6.3910, 2.5869) /0.406	0.5720 (0.1463, 2.2371) /0.422	0.386
Europe	11/165 (7%)	20/155 (13%)	0.4821 (0.2230, 1.0425) /0.064	-6.2366 (-12.7434, 0.2703) /0.060	0.5167 (0.2560, 1.0428) /0.065	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site swelling						
North America	9/118 (8%)	5/135 (4%)	2.1468 (0.6987, 6.5958) /0.182	3.9234 (-1.8285, 9.6753) /0.181	2.0593 (0.7099, 5.9734) /0.184	0.240
Europe	4/165 (2%)	7/155 (5%)	0.5253 (0.1507, 1.8308) /0.312	-2.0919 (-6.1161, 1.9323) /0.308	0.5368 (0.1603, 1.7979) /0.313	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue North America	5/118 (4%)	13/135 (10%)	0.4152 (0.1435, 1.2018) /0.105	-5.3923 (-11.5545, 0.7698) /0.086	0.4400 (0.1617, 1.1978) /0.108	0.648
Europe	1/165 (<1%)	6/155 (4%)	0.1514 (0.0180, 1.2724) /0.082	-3.2649 (-6.5245, -0.0053) /0.050	0.1566 (0.0191, 1.2857) /0.084	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pruritus						
North America	5/118 (4%)	8/135 (6%)	0.7024 (0.2234, 2.2090) /0.546	-1.6886 (-7.0806, 3.7033) /0.539	0.7150 (0.2405, 2.1261) /0.546	0.161
Europe	1/165 (<1%)	4/155 (3%)	0.2302 (0.0254, 2.0825) /0.191	-1.9746 (-4.7374, 0.7882) /0.161	0.2348 (0.0265, 2.0782) /0.193	
Rest of World	0/ 44	3/ 37 (8%)	<0.0001 (<0.0001, -) />0.999	-10.1381 (-41.5718, 21.2956) /0.527	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site erythema						
North America	4/118 (3%)	4/135 (3%)	1.1491 (0.2810, 4.6995) /0.847	0.4269 (-3.9140, 4.7677) /0.847	1.1441 (0.2925, 4.4741) /0.847	0.814
Europe	4/165 (2%)	6/155 (4%)	0.6170 (0.1708, 2.2293) /0.461	-1.4467 (-5.2846, 2.3912) /0.460	0.6263 (0.1801, 2.1772) /0.462	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asthenia North America	1/118 (<1%)	0/135	>999 (>999, >999) /NC	3.0911 (-14.7233, 20.9055) /0.734	>999 (>999, >999) /NC	0.373
Europe	9/165 (5%)	6/155 (4%)	1.4327 (0.4978, 4.1233) /0.505	1.5836 (-3.0239, 6.1910) /0.501	1.4091 (0.5135, 3.8667) /0.506	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
North America	6/118 (5%)	5/135 (4%)	1.3929 (0.4139, 4.6869) /0.593	1.3810 (-3.7043, 6.4663) /0.595	1.3729 (0.4300, 4.3830) /0.593	0.955
Europe	4/165 (2%)	2/155 (1%)	1.9006 (0.3432, 10.5268) /0.462	1.1339 (-1.8095, 4.0774) /0.450	1.8788 (0.3491, 10.1127) /0.463	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Influenza like illness						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site bruising						
North America	6/118 (5%)	5/135 (4%)	1.3929 (0.4139, 4.6869) /0.593	1.3810 (-3.7043, 6.4663) /0.595	1.3729 (0.4300, 4.3830) /0.593	0.133
Europe	2/165 (1%)	0/155	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	
Rest of World	0/ 44	1/ 37 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9614 (-35.9319, 26.0091) /0.754	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Malaise						
North America	1/118 (<1%)	2/135 (1%)				
Europe	4/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Pain						
North America	2/118 (2%)	3/135 (2%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
North America	0/118	2/135 (1%)				
Europe	0/165	5/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort						
North America	0/118	0/135				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Injection site warmth						
North America	1/118 (<1%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site anaesthesia						
North America	3/118 (3%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Chest pain						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Nodule						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site papule						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site haematoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic fatigue syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gait disturbance						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Induration						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inflammation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site mass						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site rash						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Mass						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oedema peripheral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sensation of foreign body						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Sluggishness						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temperature regulation disorder						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thirst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Xerosis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	35/118 (30%)	42/135 (31%)	0.9337 (0.5455, 1.5981) /0.803	-1.4501 (-12.8037, 9.9036) /0.802	0.9534 (0.6556, 1.3864) /0.803	0.829
Europe	58/165 (35%)	66/155 (43%)	0.7310 (0.4656, 1.1476) /0.173	-7.4291 (-18.0905, 3.2323) /0.172	0.8255 (0.6262, 1.0883) /0.174	
Rest of World	12/ 44 (27%)	12/ 37 (32%)	0.7812 (0.3003, 2.0323) /0.613	-5.1597 (-25.1768, 14.8574) /0.613	0.8409 (0.4302, 1.6436) /0.612	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	3/118 (3%)	3/135 (2%)	1.1478 (0.2272, 5.7984) /0.868	0.3202 (-3.4546, 4.0949) /0.868	1.1441 (0.2354, 5.5607) /0.867	0.462
Europe	29/165 (18%)	37/155 (24%)	0.6800 (0.3943, 1.1729) /0.166	-6.2952 (-15.1702, 2.5798) /0.164	0.7363 (0.4771, 1.1362) /0.167	
Rest of World	3/ 44 (7%)	1/ 37 (3%)	2.6341 (0.2622, 26.4586) /0.411	4.1155 (-4.9823, 13.2133) /0.375	2.5227 (0.2738, 23.2402) /0.414	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	15/118 (13%)	23/135 (17%)	0.7092 (0.3510, 1.4329) /0.338	-4.3252 (-13.0626, 4.4122) /0.332	0.7461 (0.4088, 1.3619) /0.340	0.811
Europe	5/165 (3%)	9/155 (6%)	0.5069 (0.1661, 1.5475) /0.233	-2.7761 (-7.2924, 1.7401) /0.228	0.5219 (0.1788, 1.5230) /0.234	
Rest of World	4/ 44 (9%)	6/ 37 (16%)	0.5167 (0.1340, 1.9916) /0.337	-7.1253 (-21.7271, 7.4765) /0.339	0.5606 (0.1710, 1.8376) /0.339	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroenteritis						
North America	3/118 (3%)	2/135 (1%)	1.7348 (0.2849, 10.5634) /0.550	1.0609 (-2.4347, 4.5565) /0.552	1.7161 (0.2917, 10.0958) /0.550	0.441
Europe	6/165 (4%)	12/155 (8%)	0.4497 (0.1645, 1.2293) /0.119	-4.1056 (-9.1908, 0.9797) /0.114	0.4697 (0.1807, 1.2208) /0.121	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis North America	2/118 (2%)	5/135 (4%)	0.4483 (0.0853, 2.3548) /0.343	-2.0088 (-5.9550, 1.9375) /0.318	0.4576 (0.0905, 2.3150) /0.345	0.919
Europe	4/165 (2%)	6/155 (4%)	0.6170 (0.1708, 2.2293) /0.461	-1.4467 (-5.2846, 2.3912) /0.460	0.6263 (0.1801, 2.1772) /0.462	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
North America	2/118 (2%)	4/135 (3%)				
Europe	2/165 (1%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Bronchitis						
North America	3/118 (3%)	2/135 (1%)				
Europe	3/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea North America	4/118 (3%)	4/135 (3%)				
Europe	4/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Influenza North America	3/118 (3%)	1/135 (<1%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sinusitis						
North America	1/118 (<1%)	3/135 (2%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				
Chlamydial infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	5/165 (3%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/118	0/135				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/118	0/135				
Europe	3/165 (2%)	6/155 (4%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis						
North America	1/118 (<1%)	0/135				
Europe	3/165 (2%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				
Conjunctivitis						
North America	0/118	2/135 (1%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	1/ 44 (2%)	0/ 37				
Oral herpes						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis						
North America	2/118 (2%)	2/135 (1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Viral infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	3/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	1/118 (<1%)	3/135 (2%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Folliculitis						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Tonsillitis						
North America	0/118	0/135				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes simplex						
North America	1/118 (<1%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Hordeolum						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Ear infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Gingivitis						
North America	0/118	0/135				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Herpes zoster						
North America	0/118	0/135				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Onychomycosis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis gonococcal						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth infection						
North America	0/118	0/135				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				
Furuncle						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	3/ 44 (7%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis externa						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Secondary syphilis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Tooth abscess						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethritis gonococcal						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Body tinea						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Helicobacter infection						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphogranulo ma venereum						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Molluscum contagiosum						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Paronychia						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Postoperative wound infection						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin infection						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal infection						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea infection						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod infestation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchitis viral						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Candida infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Cellulitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chronic sinusitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis viral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cutaneous blastomycosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Cystitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterovirus infection						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema migrans						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
External ear cellulitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis viral						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital herpes simplex						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival abscess						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Groin abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis E						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Infectious mononucleosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Labyrinthitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Laryngitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Mycoplasma infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Otitis media acute						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Pericoronitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peritonsillar abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis bacterial						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis mycoplasmal						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis mycoplasmal						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal abscess						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Schistosomiasis cutaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Syphilis genital						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Tinea capitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinea cruris						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Tinea pedis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tracheitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Tracheobronchitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Trichomoniasis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureaplasma infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Varicella						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Viral rash						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Viral rhinitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	20/118 (17%)	32/135 (24%)	0.6569 (0.3522, 1.2253) /0.186	-6.7546 (-16.6180, 3.1089) /0.180	0.7150 (0.4332, 1.1802) /0.190	0.542
Europe	24/165 (15%)	29/155 (19%)	0.7395 (0.4092, 1.3366) /0.318	-4.1642 (-12.3271, 3.9986) /0.317	0.7774 (0.4742, 1.2746) /0.318	
Rest of World	8/ 44 (18%)	5/ 37 (14%)	1.4222 (0.4222, 4.7913) /0.570	4.6683 (-11.1816, 20.5182) /0.564	1.3455 (0.4812, 3.7622) /0.572	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea North America	9/118 (8%)	7/135 (5%)	1.5098 (0.5443, 4.1880) /0.429	2.4419 (-3.6347, 8.5186) /0.431	1.4709 (0.5653, 3.8276) /0.429	0.619
Europe	9/165 (5%)	8/155 (5%)	1.0601 (0.3984, 2.8208) /0.907	0.2933 (-4.6198, 5.2063) /0.907	1.0568 (0.4183, 2.6699) /0.907	
Rest of World	2/ 44 (5%)	3/ 37 (8%)	0.5397 (0.0852, 3.4167) /0.512	-3.5627 (-14.2975, 7.1722) /0.515	0.5606 (0.0989, 3.1779) /0.513	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nausea North America	4/118 (3%)	11/135 (8%)	0.3955 (0.1225, 1.2773) /0.121	-4.7583 (-10.4115, 0.8948) /0.099	0.4160 (0.1361, 1.2717) /0.124	0.271
Europe	0/165	4/155 (3%)	<0.0001 (<0.0001, -) />0.999	-4.8429 (-20.7594, 11.0736) /0.551	<0.0001 (<0.0001, -) />0.999	
Rest of World	1/ 44 (2%)	2/ 37 (5%)	0.4070 (0.0354, 4.6766) /0.470	-3.1327 (-11.6461, 5.3807) /0.471	0.4205 (0.0397, 4.4544) /0.472	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
North America	1/118 (<1%)	2/135 (1%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				
Abdominal pain						
North America	0/118	3/135 (2%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	5/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				
Constipation						
North America	0/118	3/135 (2%)				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	2/118 (2%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Toothache						
North America	1/118 (<1%)	0/135				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	0/118	2/135 (1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Abdominal pain upper						
North America	3/118 (3%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroesophageal reflux disease						
North America	2/118 (2%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain lower						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Flatulence						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastritis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Dry mouth						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gingival pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Inguinal hernia						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Irritable bowel syndrome						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Noninfective gingivitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal discharge						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rectal haemorrhage						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal hernia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal tenderness						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Anal fistula						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal pruritus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Angular cheilitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cheilitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dental caries						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enterocolitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Food poisoning						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastric disorder						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastrointestinal disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival hypertrophy						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Haematemesis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematochezia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hiatus hernia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertrophic anal papilla						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia oral						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Large intestine polyp						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mouth ulceration						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Oesophagitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pancreatitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Perianal erythema						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctalgia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Tooth disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	16/118 (14%)	20/135 (15%)	0.9020 (0.4437, 1.8335) /0.776	-1.2555 (-9.8617, 7.3507) /0.775	0.9153 (0.4977, 1.6832) /0.776	0.700
Europe	22/165 (13%)	28/155 (18%)	0.6978 (0.3801, 1.2809) /0.246	-4.7312 (-12.7053, 3.2429) /0.245	0.7381 (0.4416, 1.2335) /0.246	
Rest of World	3/ 44 (7%)	5/ 37 (14%)	0.4683 (0.1041, 2.1075) /0.323	-6.6953 (-19.9923, 6.6017) /0.324	0.5045 (0.1291, 1.9716) /0.325	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	4/118 (3%)	5/135 (4%)	0.9123 (0.2392, 3.4792) /0.893	-0.3139 (-4.8757, 4.2479) /0.893	0.9153 (0.2516, 3.3295) /0.893	0.932
Europe	8/165 (5%)	11/155 (7%)	0.6671 (0.2610, 1.7049) /0.398	-2.2483 (-7.4522, 2.9556) /0.397	0.6832 (0.2823, 1.6536) /0.398	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	5/118 (4%)	5/135 (4%)	1.1504 (0.3247, 4.0759) /0.828	0.5336 (-4.2995, 5.3666) /0.829	1.1441 (0.3395, 3.8548) /0.828	0.879
Europe	3/165 (2%)	4/155 (3%)	0.6991 (0.1539, 3.1749) /0.643	-0.7625 (-3.9853, 2.4604) /0.643	0.7045 (0.1603, 3.0975) /0.643	
Rest of World	2/ 44 (5%)	2/ 37 (5%)	0.8333 (0.1116, 6.2234) /0.859	-0.8600 (-10.3977, 8.6778) /0.860	0.8409 (0.1244, 5.6820) /0.859	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
North America	3/118 (3%)	6/135 (4%)				
Europe	4/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				
Myalgia						
North America	5/118 (4%)	1/135 (<1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
North America	0/118	0/135				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Muscle spasms						
North America	0/118	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Neck pain						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Tendonitis						
North America	1/118 (<1%)	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
Bursitis						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Joint contracture						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Arthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical spinal stenosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exostosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Femoroacetabular impingement						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Flank pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint range of motion decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint stiffness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint swelling						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle tightness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal stiffness						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteochondritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Osteopenia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Scoliosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Spinal osteoarthritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Synovial cyst						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Synovitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Temporomandibular joint syndrome						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tendon disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Tenosynovitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Trigger finger						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	23/118 (19%)	21/135 (16%)	1.3143 (0.6853, 2.5206) /0.411	3.9360 (-5.4696, 13.3415) /0.412	1.2530 (0.7320, 2.1449) /0.411	0.057
Europe	13/165 (8%)	20/155 (13%)	0.5773 (0.2766, 1.2048) /0.143	-5.0244 (-11.7140, 1.6651) /0.141	0.6106 (0.3147, 1.1849) /0.145	
Rest of World	3/ 44 (7%)	8/ 37 (22%)	0.2652 (0.0648, 1.0859) /0.065	-14.8034 (-30.0157, 0.4089) /0.056	0.3153 (0.0901, 1.1037) /0.071	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus						
North America	4/118 (3%)	2/135 (1%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	1/ 44 (2%)	2/ 37 (5%)				
Rash						
North America	2/118 (2%)	5/135 (4%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	2/ 44 (5%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eczema						
North America	1/118 (<1%)	0/135				
Europe	2/165 (1%)	5/155 (3%)				
Rest of World	0/ 44	2/ 37 (5%)				
Alopecia						
North America	3/118 (3%)	0/135				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acne						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	2/ 37 (5%)				
Skin lesion						
North America	1/118 (<1%)	3/135 (2%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Seborrhoeic dermatitis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	3/118 (3%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dermal cyst						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry skin						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperhidrosis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Rash erythematous						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin exfoliation						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Skin mass						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urticaria						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Androgenetic alopecia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chloasma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Cold sweat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis atopic						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Drug eruption						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erythema						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Intertrigo						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Keratosis pilaris						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Macule						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Miliaria						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Nail bed inflammation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Petechiae						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pigmentation disorder						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Pityriasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pityriasis rosea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pruritus generalised						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Psoriasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Purpura						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rash morbilliform						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin discolouration						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin fissures						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Skin hypertrophy						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin irritation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Solar dermatitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	14/118 (12%)	19/135 (14%)	0.8219 (0.3924, 1.7214) /0.603	-2.2097 (-10.4833, 6.0640) /0.601	0.8430 (0.4424, 1.6062) /0.604	0.898
Europe	14/165 (8%)	17/155 (11%)	0.7526 (0.3576, 1.5839) /0.454	-2.4829 (-8.9851, 4.0193) /0.454	0.7736 (0.3949, 1.5157) /0.454	
Rest of World	4/ 44 (9%)	3/ 37 (8%)	1.1333 (0.2369, 5.4215) /0.875	0.9828 (-11.2446, 13.2102) /0.875	1.1212 (0.2679, 4.6931) /0.876	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
North America	5/118 (4%)	8/135 (6%)	0.7024 (0.2234, 2.2090) /0.546	-1.6886 (-7.0806, 3.7033) /0.539	0.7150 (0.2405, 2.1261) /0.546	0.990
Europe	5/165 (3%)	7/155 (5%)	0.6607 (0.2052, 2.1271) /0.487	-1.4858 (-5.6725, 2.7009) /0.487	0.6710 (0.2175, 2.0699) /0.488	
Rest of World	3/ 44 (7%)	4/ 37 (11%)	0.6037 (0.1261, 2.8887) /0.527	-3.9926 (-16.4656, 8.4804) /0.530	0.6307 (0.1507, 2.6399) /0.528	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	2/118 (2%)	3/135 (2%)				
Europe	4/165 (2%)	5/155 (3%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
North America	2/118 (2%)	5/135 (4%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	3/118 (3%)	3/135 (2%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Epistaxis						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthma						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Catarrh						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspnoea						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Oropharyngeal discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Productive cough						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rales						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinorrhoea						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Sleep apnoea syndrome						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bronchospasm						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dry throat						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoptysis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Interstitial lung disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal oedema						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nasal septum deviation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Painful respiration						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pleuritic pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract congestion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	18/118 (15%)	11/135 (8%)	2.0291 (0.9163, 4.4933) /0.081	7.1061 (-0.8551, 15.0673) /0.080	1.8721 (0.9220, 3.8012) /0.083	0.071
Europe	15/165 (9%)	21/155 (14%)	0.6381 (0.3161, 1.2880) /0.210	-4.4575 (-11.4051, 2.4901) /0.209	0.6710 (0.3591, 1.2539) /0.211	
Rest of World	1/ 44 (2%)	2/ 37 (5%)	0.4070 (0.0354, 4.6766) /0.470	-3.1327 (-11.6461, 5.3807) /0.471	0.4205 (0.0397, 4.4544) /0.472	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Headache North America	8/118 (7%)	4/135 (3%)	2.3818 (0.6985, 8.1219) /0.166	3.8167 (-1.5458, 9.1792) /0.163	2.2881 (0.7069, 7.4058) /0.167	0.115
Europe	9/165 (5%)	13/155 (8%)	0.6302 (0.2614, 1.5190) /0.304	-2.9326 (-8.5047, 2.6396) /0.302	0.6503 (0.2861, 1.4783) /0.304	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dizziness						
North America	7/118 (6%)	2/135 (1%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	2/ 37 (5%)				
Paraesthesia						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Migraine North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Presyncope North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Somnolence						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Lethargy						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Amnesia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Burning sensation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Carpal tunnel syndrome						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cervical radiculopathy						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dysarthria						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysgeusia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Head discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperaesthesia ^a						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hypersomnia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoaesthesia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contractions involuntary						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodic limb movement disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Polyneuropathy						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Sciatica						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tension headache						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	7/118 (6%)	18/135 (13%)	0.4099 (0.1649, 1.0192) /0.055	-7.4011 (-14.5459, -0.2563) /0.042	0.4449 (0.1926, 1.0279) /0.058	0.569
Europe	11/165 (7%)	13/155 (8%)	0.7802 (0.3386, 1.7977) /0.560	-1.7204 (-7.5109, 4.0700) /0.560	0.7949 (0.3671, 1.7209) /0.560	
Rest of World	2/ 44 (5%)	2/ 37 (5%)	0.8333 (0.1116, 6.2234) /0.859	-0.8600 (-10.3977, 8.6778) /0.860	0.8409 (0.1244, 5.6820) /0.859	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia North America	2/118 (2%)	11/135 (8%)	0.1944 (0.0422, 0.8956) /0.036	-6.4532 (-11.6224, -1.2840) /0.014	0.2080 (0.0471, 0.9195) /0.038	0.185
Europe	3/165 (2%)	5/155 (3%)	0.5556 (0.1305, 2.3648) /0.426	-1.4076 (-4.8562, 2.0410) /0.424	0.5636 (0.1370, 2.3190) /0.427	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anxiety						
North America	1/118 (<1%)	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Abnormal dreams						
North America	0/118	3/135 (2%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depressed mood						
North America	0/118	0/135				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Libido decreased						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Nightmare						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Depression						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug abuse						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Irritability						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Adjustment disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with mixed anxiety and depressed mood						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Agoraphobia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Emotional distress						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Loss of libido						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Mood swings						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervousness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Post-traumatic stress disorder						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Stress North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	7/118 (6%)	18/135 (13%)	0.4099 (0.1649, 1.0192) /0.055	-7.4011 (-14.5459, -0.2563) /0.042	0.4449 (0.1926, 1.0279) /0.058	0.515
Europe	7/165 (4%)	16/155 (10%)	0.3849 (0.1539, 0.9629) /0.041	-6.0802 (-11.7723, -0.3880) /0.036	0.4110 (0.1738, 0.9719) /0.043	
Rest of World	2/ 44 (5%)	1/ 37 (3%)	1.7143 (0.1492, 19.6953) /0.665	1.8428 (-6.2308, 9.9163) /0.655	1.6818 (0.1587, 17.8176) /0.666	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	0/118	3/135 (2%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	4/118 (3%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Contusion						
North America	0/118	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	0/118	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Skin laceration						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Animal bite						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Skin abrasion						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod sting						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Bone contusion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Concussion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epicondylitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Fall						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Foot fracture						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Heat stroke						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection related reaction						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury corneal						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Lip injury						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nail injury						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Procedural pain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Sunburn						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thermal burn						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Traumatic haematoma						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ulna fracture						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Vaccination complication						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	8/118 (7%)	6/135 (4%)	1.5636 (0.5264, 4.6443) /0.421	2.3352 (-3.3796, 8.0501) /0.423	1.5254 (0.5450, 4.2697) /0.421	0.074
Europe	3/165 (2%)	11/155 (7%)	0.2424 (0.0663, 0.8861) /0.032	-5.2786 (-9.8059, -0.7513) /0.022	0.2562 (0.0728, 0.9011) /0.034	
Rest of World	3/ 44 (7%)	3/ 37 (8%)	0.8293 (0.1571, 4.3772) /0.825	-1.2899 (-12.8148, 10.2350) /0.826	0.8409 (0.1804, 3.9203) /0.825	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/118	2/135 (1%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood glucose increased						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Low density lipoprotein increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Aspartate aminotransferase increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood bilirubin unconjugated increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatinine increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood triglycerides increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chlamydia test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematocrit increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemoglobin increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intraocular pressure increased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D decreased						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	2/118 (2%)	2/135 (1%)	1.1465 (0.1590, 8.2687) /0.892	0.2134 (-2.8813, 3.3082) /0.892	1.1441 (0.1637, 7.9959) /0.892	0.443
Europe	6/165 (4%)	12/155 (8%)	0.4497 (0.1645, 1.2293) /0.119	-4.1056 (-9.1908, 0.9797) /0.114	0.4697 (0.1807, 1.2208) /0.121	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rest of World	0/ 44	1/ 37 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9614 (-35.9319, 26.0091) /0.754	<0.0001 (<0.0001, -) />0.999	
Anogenital warts						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	5/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin papilloma						
North America	0/118	0/135				
Europe	0/165	6/155 (4%)				
Rest of World	0/ 44	0/ 37				
Acrochordon						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Basal cell carcinoma						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Fibroma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Kaposi's sarcoma						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Lipoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipoma of breast						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urethral papilloma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Uterine leiomyoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	2/118 (2%)	5/135 (4%)	0.4483 (0.0853, 2.3548) /0.343	-2.0088 (-5.9550, 1.9375) /0.318	0.4576 (0.0905, 2.3150) /0.345	0.462
Europe	8/165 (5%)	5/155 (3%)	1.5287 (0.4891, 4.7776) /0.465	1.6227 (-2.6759, 5.9212) /0.459	1.5030 (0.5025, 4.4957) /0.466	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
North America	2/118 (2%)	3/135 (2%)				
Europe	6/165 (4%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Flushing						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haematoma North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral venous disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hot flush						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Hypotension						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral coldness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Varicose vein						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	2/118 (2%)	6/135 (4%)	0.3707 (0.0734, 1.8728) /0.230	-2.7495 (-6.9339, 1.4348) /0.198	0.3814 (0.0785, 1.8536) /0.232	0.170
Europe	7/165 (4%)	4/155 (3%)	1.6725 (0.4799, 5.8291) /0.419	1.6618 (-2.2991, 5.6227) /0.411	1.6439 (0.4908, 5.5060) /0.420	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	1/118 (<1%)	3/135 (2%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Prostatomegaly						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrophic vulvovaginitis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Balanoposthitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Breast cyst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Breast pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Genital erythema						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menorrhagia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Penile pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular cyst						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular mass						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Testis discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Uterine polyp						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaginal discharge						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	6/118 (5%)	5/135 (4%)	1.3929 (0.4139, 4.6869) /0.593	1.3810 (-3.7043, 6.4663) /0.595	1.3729 (0.4300, 4.3830) /0.593	0.164
Europe	2/165 (1%)	3/155 (2%)	0.6217 (0.1025, 3.7714) /0.605	-0.7234 (-3.4605, 2.0138) /0.604	0.6263 (0.1061, 3.6978) /0.605	
Rest of World	0/ 44	2/ 37 (5%)	<0.0001 (<0.0001, -) />0.999	-7.5584 (-38.7241, 23.6072) /0.635	<0.0001 (<0.0001, -) />0.999	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Vertigo						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerumen impaction						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ear discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Excessive cerumen production						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Deafness neurosensory						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Ear pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eustachian tube dysfunction						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypoacusis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/118	3/135 (2%)				
Europe	2/165 (1%)	7/155 (5%)				
Rest of World	2/ 44 (5%)	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dysuria						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Micturition urgency						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nocturia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Haematuria						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Micturition disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nephrolithiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nephropathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pollakiuria						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Urethral disorder						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Urinary tract disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	1/118 (<1%)	5/135 (4%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Conjunctivitis allergic						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dry eye						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Eye pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eyelid cyst						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Glaucoma						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iritis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Mydriasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ocular hyperaemia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Pterygium						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vision blurred						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitreous floaters						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	4/118 (3%)	5/135 (4%)				
Europe	0/165	3/155 (2%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Decreased appetite						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gluten sensitivity						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Gout						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperglycaemi ^a						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hyperlipasaemia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hypokalaemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Obesity						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	4/118 (3%)	0/135				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	4/118 (3%)	0/135				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypersensitivity						
North America	0/118	0/135				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anaemia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymph node pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lymphadenopathy						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Endocrine disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypogonadism						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Goitre						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Tachycardia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cholelithiasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Hepatomegaly						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Social circumstances						
Any Event						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Menopause						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Stress at work						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 1

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type V hyperlipidaemia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	66/118 (56%)	60/135 (44%)	1.5865 (0.9649, 2.6087) /0.069	11.4878 (-0.7801, 23.7556) /0.066	1.2585 (0.9826, 1.6118) /0.069	0.043
Europe	70/165 (42%)	67/155 (43%)	0.9678 (0.6214, 1.5073) /0.885	-0.8016 (-11.6500, 10.0469) /0.885	0.9815 (0.7619, 1.2643) /0.885	
Rest of World	20/ 44 (45%)	24/ 37 (65%)	0.4514 (0.1838, 1.1088) /0.083	-19.4103 (-40.6959, 1.8753) /0.074	0.7008 (0.4691, 1.0467) /0.082	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	44/118 (37%)	43/135 (32%)	1.2722 (0.7564, 2.1396) /0.364	5.4363 (-6.3065, 17.1790) /0.364	1.1707 (0.8332, 1.6448) /0.364	0.647
Europe	48/165 (29%)	48/155 (31%)	0.9145 (0.5668, 1.4755) /0.714	-1.8768 (-11.9271, 8.1734) /0.714	0.9394 (0.6722, 1.3128) /0.714	
Rest of World	15/ 44 (34%)	13/ 37 (35%)	0.9549 (0.3810, 2.3932) /0.922	-1.0442 (-21.8477, 19.7592) /0.922	0.9703 (0.5323, 1.7686) /0.922	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Injection site pain						
North America	40/118 (34%)	39/135 (29%)	1.2623 (0.7410, 2.1505) /0.391	5.0094 (-6.4537, 16.4725) /0.392	1.1734 (0.8142, 1.6910) /0.391	0.785
Europe	44/165 (27%)	42/155 (27%)	0.9784 (0.5967, 1.6042) /0.931	-0.4301 (-10.1505, 9.2903) /0.931	0.9841 (0.6856, 1.4127) /0.931	
Rest of World	15/ 44 (34%)	11/ 37 (30%)	1.2226 (0.4771, 3.1330) /0.676	4.3612 (-15.9629, 24.6852) /0.674	1.1467 (0.6025, 2.1825) /0.677	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site nodule						
North America	0/118	4/135 (3%)	<0.0001 (<0.0001, -) />0.999	-5.2135 (-23.9031, 13.4760) /0.585	<0.0001 (<0.0001, -) />0.999	0.493
Europe	2/165 (1%)	8/155 (5%)	0.2255 (0.0471, 1.0788) /0.062	-3.9492 (-7.8117, -0.0866) /0.045	0.2348 (0.0507, 1.0888) /0.064	
Rest of World	1/ 44 (2%)	3/ 37 (8%)	0.2636 (0.0262, 2.6485) /0.257	-5.8354 (-15.6714, 4.0006) /0.245	0.2803 (0.0304, 2.5822) /0.262	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	5/118 (4%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site induration						
North America	2/118 (2%)	1/135 (<1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	1/118 (<1%)	3/135 (2%)				
Europe	4/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				
Injection site swelling						
North America	4/118 (3%)	5/135 (4%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	3/ 44 (7%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Injection site pruritus						
North America	2/118 (2%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site erythema						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Asthenia						
North America	2/118 (2%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Influenza like illness						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site bruising						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Malaise						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site haematoma						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Discomfort						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site warmth						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site reaction						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Chest pain						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Feeling hot						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Nodule						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vessel puncture site haematoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gait disturbance						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Non-cardiac chest pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Peripheral swelling						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discharge						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site fibrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site hypersensitivity						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site necrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infections and infestations						
Any Event						
North America	24/118 (20%)	33/135 (24%)	0.7892 (0.4349, 1.4320) /0.436	-4.1055 (-14.3671, 6.1561) /0.433	0.8320 (0.5231, 1.3235) /0.438	0.958
Europe	32/165 (19%)	33/155 (21%)	0.8895 (0.5159, 1.5338) /0.674	-1.8964 (-10.7240, 6.9312) /0.674	0.9109 (0.5902, 1.4060) /0.674	
Rest of World	10/ 44 (23%)	10/ 37 (27%)	0.7941 (0.2887, 2.1841) /0.655	-4.2998 (-23.2230, 14.6235) /0.656	0.8409 (0.3934, 1.7976) /0.655	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasopharyngitis						
North America	2/118 (2%)	4/135 (3%)	0.5647 (0.1015, 3.1397) /0.514	-1.2680 (-4.9566, 2.4205) /0.500	0.5720 (0.1067, 3.0672) /0.514	0.227
Europe	10/165 (6%)	3/155 (2%)	3.2688 (0.8825, 12.1083) /0.076	4.1251 (-0.1127, 8.3629) /0.056	3.1313 (0.8781, 11.1662) /0.078	
Rest of World	1/ 44 (2%)	1/ 37 (3%)	0.8372 (0.0506, 13.8636) /0.901	-0.4300 (-7.2632, 6.4033) /0.902	0.8409 (0.0545, 12.9856) /0.901	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Upper respiratory tract infection						
North America	6/118 (5%)	9/135 (7%)	0.7500 (0.2588, 2.1732) /0.596	-1.5819 (-7.3627, 4.1988) /0.592	0.7627 (0.2797, 2.0796) /0.597	0.969
Europe	2/165 (1%)	3/155 (2%)	0.6217 (0.1025, 3.7714) /0.605	-0.7234 (-3.4605, 2.0138) /0.604	0.6263 (0.1061, 3.6978) /0.605	
Rest of World	3/ 44 (7%)	3/ 37 (8%)	0.8293 (0.1571, 4.3772) /0.825	-1.2899 (-12.8148, 10.2350) /0.826	0.8409 (0.1804, 3.9203) /0.825	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
North America	1/118 (<1%)	5/135 (4%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				
Pharyngitis						
North America	1/118 (<1%)	2/135 (1%)				
Europe	3/165 (2%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Syphilis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				
Bronchitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	4/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gonorrhoea						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Influenza						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Sinusitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Chlamydial infection						
North America	0/118	0/135				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory tract infection viral						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Conjunctivitis						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urinary tract infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				
Oral herpes						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urethritis						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Viral infection						
North America	0/118	1/135 (<1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral upper respiratory tract infection						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Folliculitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Tonsillitis						
North America	0/118	1/135 (<1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tinea versicolour						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Ear infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fungal skin infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis viral						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Herpes zoster						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Proctitis gonococcal						
North America	2/118 (2%)	4/135 (3%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Furuncle						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lower respiratory tract infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tooth abscess						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Urethritis gonococcal						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal chlamydia infection						
North America	2/118 (2%)	4/135 (3%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body tinea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Mycoplasma genitalium infection						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oral candidiasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal gonococcal infection						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Paronychia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Pneumonia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Viral pharyngitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acarodermatitis						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Cellulitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cystitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Diverticulitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Enteritis infectious						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Escherichia urinary tract infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Genital herpes						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Laryngitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngeal chlamydia infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngitis streptococcal						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pharyngotonsillitis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Primary syphilis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pulpitis dental						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Staphylococcal skin infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tracheitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Ureaplasma infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Varicella North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Urethritis chlamydial North America	0/118	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Orchitis						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Shigella infection						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abscess North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Abscess limb North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Asymptomatic bacteriuria						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial diarrhoea						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial rhinitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Bacterial vaginosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest wall abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatophytosis of nail						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Device related infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea infectious						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear infection bacterial						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Enterobiasis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epididymitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Escherichia infection						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Escherichia coli						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genital candidiasis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Genitourinary tract infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Infection						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Lice infestation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oesophageal candidiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ophthalmic herpes zoster						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Perirectal abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Proctitis chlamydial						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pulmonary tuberculosis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Sialoadenitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin bacterial infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Subcutaneous abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vulvovaginal mycotic infection						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	10/118 (8%)	10/135 (7%)	1.1574 (0.4642, 2.8856) /0.754	1.0672 (-5.6237, 7.7580) /0.755	1.1441 (0.4934, 2.6527) /0.754	0.031
Europe	4/165 (2%)	15/155 (10%)	0.2319 (0.0752, 0.7149) /0.011	-7.2532 (-12.4657, -2.0407) /0.006	0.2505 (0.0850, 0.7383) /0.012	
Rest of World	3/ 44 (7%)	1/ 37 (3%)	2.6341 (0.2622, 26.4586) /0.411	4.1155 (-4.9823, 13.2133) /0.375	2.5227 (0.2738, 23.2402) /0.414	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diarrhoea						
North America	3/118 (3%)	2/135 (1%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				
Nausea						
North America	3/118 (3%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dyspepsia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Abdominal pain						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoids						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Constipation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal distension						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Toothache						
North America	1/118 (<1%)	0/135				
Europe	0/165	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vomiting						
North America	2/118 (2%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Abdominal pain upper						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Gastroesophageal reflux disease						
North America	0/118	2/135 (1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal discomfort						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital dysplasia						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Gastritis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Inguinal hernia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Anal fistula						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Colitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Anal fissure						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Crohn's disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gingival ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Glossitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoids thrombosed						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intestinal polyp						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Periodontal disease						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Proctitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tongue ulceration						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	9/118 (8%)	10/135 (7%)	1.0321 (0.4046, 2.6328) /0.947	0.2197 (-6.2959, 6.7353) /0.947	1.0297 (0.4331, 2.4479) /0.947	0.736
Europe	8/165 (5%)	11/155 (7%)	0.6671 (0.2610, 1.7049) /0.398	-2.2483 (-7.4522, 2.9556) /0.397	0.6832 (0.2823, 1.6536) /0.398	
Rest of World	3/ 44 (7%)	2/ 37 (5%)	1.2805 (0.2023, 8.1045) /0.793	1.4128 (-9.0062, 11.8318) /0.790	1.2614 (0.2225, 7.1503) /0.793	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Back pain						
North America	0/118	1/135 (<1%)				
Europe	3/165 (2%)	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Arthralgia						
North America	3/118 (3%)	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pain in extremity						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Myalgia						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal pain						
North America	3/118 (3%)	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle contracture						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Muscle spasms						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal chest pain						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				
Neck pain						
North America	0/118	0/135				
Europe	1/165 (<1%)	2/155 (1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tendonitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Exostosis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscular weakness						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Synovial cyst						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteoarthritis						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Groin pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in jaw						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Periarthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Plantar fasciitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	5/118 (4%)	9/135 (7%)	0.6195 (0.2017, 1.9030) /0.403	-2.4294 (-7.9895, 3.1308) /0.392	0.6356 (0.2191, 1.8437) /0.404	0.424
Europe	7/165 (4%)	5/155 (3%)	1.3291 (0.4128, 4.2789) /0.633	1.0166 (-3.1300, 5.1633) /0.631	1.3151 (0.4263, 4.0570) /0.634	
Rest of World	3/ 44 (7%)	1/ 37 (3%)	2.6341 (0.2622, 26.4586) /0.411	4.1155 (-4.9823, 13.2133) /0.375	2.5227 (0.2738, 23.2402) /0.414	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pruritus						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Rash						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Eczema						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Alopecia						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin lesion						
North America	0/118	0/135				
Europe	3/165 (2%)	0/155				
Rest of World	0/ 44	0/ 37				
Dermatitis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Night sweats						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dermal cyst						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Dermatitis contact						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hyperhidrosis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Urticaria						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Skin fissures						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Granuloma annulare						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hand dermatitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lichen sclerosus						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Pain of skin						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash maculo-papular						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rash pruritic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Rash vesicular						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Skin swelling						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	4/118 (3%)	7/135 (5%)	0.6416 (0.1831, 2.2487) /0.488	-1.7954 (-6.7603, 3.1696) /0.478	0.6538 (0.1962, 2.1779) /0.489	0.555
Europe	1/165 (<1%)	5/155 (3%)	0.1829 (0.0211, 1.5837) /0.123	-2.6197 (-5.6429, 0.4034) /0.089	0.1879 (0.0222, 1.5902) /0.125	
Rest of World	2/ 44 (5%)	3/ 37 (8%)	0.5397 (0.0852, 3.4167) /0.512	-3.5627 (-14.2975, 7.1722) /0.515	0.5606 (0.0989, 3.1779) /0.513	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cough						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oropharyngeal pain						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sinus congestion						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal congestion						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rhinitis allergic						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	3/155 (2%)				
Rest of World	0/ 44	0/ 37				
Epistaxis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Asthma						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Dyspnoea						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Productive cough						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep apnoea syndrome						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Haemoptysis						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nasal discomfort						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Snoring						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Preferred Term						

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Nervous system disorders						
Any Event						
North America	6/118 (5%)	7/135 (5%)	0.9796 (0.3198, 3.0009) /0.971	-0.1004 (-5.5503, 5.3494) /0.971	0.9806 (0.3390, 2.8364) /0.971	0.572
Europe	3/165 (2%)	7/155 (5%)	0.3915 (0.0994, 1.5420) /0.180	-2.6979 (-6.5506, 1.1547) /0.170	0.4026 (0.1060, 1.5293) /0.182	
Rest of World	2/ 44 (5%)	3/ 37 (8%)	0.5397 (0.0852, 3.4167) /0.512	-3.5627 (-14.2975, 7.1722) /0.515	0.5606 (0.0989, 3.1779) /0.513	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
<hr/>						
Headache						
North America	3/118 (3%)	4/135 (3%)				
Europe	1/165 (<1%)	3/155 (2%)				
Rest of World	0/ 44	3/ 37 (8%)				
Dizziness						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	1/ 44 (2%)	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Presyncope						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Head discomfort						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypoaesthesia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Sciatica						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tension headache						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Syncope						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebral infarction						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Hypertonia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neuropathy peripheral						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Radiculopathy						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Psychiatric disorders						
Any Event						
North America	7/118 (6%)	4/135 (3%)	2.0653 (0.5892, 7.2392) /0.257	2.9692 (-2.1638, 8.1023) /0.257	2.0021 (0.6010, 6.6698) /0.258	0.740
Europe	6/165 (4%)	3/155 (2%)	1.9119 (0.4698, 7.7815) /0.365	1.7009 (-1.8855, 5.2873) /0.353	1.8788 (0.4782, 7.3823) /0.366	
Rest of World	2/ 44 (5%)	2/ 37 (5%)	0.8333 (0.1116, 6.2234) /0.859	-0.8600 (-10.3977, 8.6778) /0.860	0.8409 (0.1244, 5.6820) /0.859	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Insomnia						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	2/ 44 (5%)	0/ 37				
Anxiety						
North America	4/118 (3%)	2/135 (1%)				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abnormal dreams						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Depression						
North America	2/118 (2%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Panic attack						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Adjustment disorder with depressed mood						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Restlessness						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	7/118 (6%)	13/135 (10%)	0.5918 (0.2279, 1.5366) /0.281	-3.6974 (-10.2495, 2.8546) /0.269	0.6160 (0.2542, 1.4927) /0.283	0.519
Europe	5/165 (3%)	6/155 (4%)	0.7760 (0.2320, 2.5962) /0.681	-0.8407 (-4.8486, 3.1673) /0.681	0.7828 (0.2438, 2.5132) /0.681	
Rest of World	1/ 44 (2%)	4/ 37 (11%)	0.1919 (0.0205, 1.7982) /0.148	-8.5381 (-19.4696, 2.3934) /0.126	0.2102 (0.0246, 1.7998) /0.155	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthropod bite						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Limb injury						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Contusion						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ligament sprain						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Exposure to communicable disease						
North America	2/118 (2%)	3/135 (2%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle strain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Skin laceration						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin abrasion						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Arthropod sting						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Heat stroke						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal foreign body						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Road traffic accident						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vaccination complication						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Rib fracture						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint injury						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				
Meniscus injury						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Wrist fracture						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Burns second degree						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chemical burns of eye						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Clavicle fracture						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Corneal abrasion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fibula fracture						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Head injury						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Joint dislocation						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Scapula fracture						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	1/118 (<1%)	4/135 (3%)				
Europe	1/165 (<1%)	4/155 (3%)				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Alanine aminotransferase increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood creatine phosphokinase increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Weight increased						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood cholesterol increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Lipase increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
CD4 lymphocytes decreased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Campylobacter test positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Creatinine renal clearance decreased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Culture urine positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hepatic enzyme increased						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Muscle enzyme increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Parasite stool test positive						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Shigella test positive						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anogenital warts						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fibrous histiocytoma						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Vascular disorders						
Any Event						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	2/ 37 (5%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypertension						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blood pressure inadequately controlled						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	1/ 37 (3%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Thrombophlebitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
Europe	5/165 (3%)	3/155 (2%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Erectile dysfunction						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Testicular cyst						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign prostatic hyperplasia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cervical dysplasia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haematospermi ^a						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile burning sensation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Penile discharge						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Priapism						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Prostatitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Testicular torsion						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tinnitus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
North America	2/118 (2%)	1/135 (<1%)				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Dysuria						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Pollakiuria						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
North America	0/118	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				
Leukocyturia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ureterolithiasis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	2/118 (2%)	0/135				
Europe	2/165 (1%)	4/155 (3%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharitis						
North America	1/118 (<1%)	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Conjunctivitis allergic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Blepharospasm						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Cataract						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chalazion						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Diplopia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eyelid oedema						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Retinal detachment						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ulcerative keratitis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	0/118	3/135 (2%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Vitamin D deficiency						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Obesity						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Type 2 diabetes mellitus						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cachexia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	3/165 (2%)	4/155 (3%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Seasonal allergy						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Food allergy						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Drug hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Iron deficiency anaemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Neutropenia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	1/118 (<1%)	3/135 (2%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Palpitations						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Tachycardia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Angina pectoris						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrial fibrillation						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cardiac aneurysm						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Ventricular extrasystoles						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatobiliary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Jaundice						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Congenital, familial and genetic disorders						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	0/165	2/155 (1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Atrial septal defect						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Benign familial pemphigus						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 2

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hydrocele						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	6/118 (5%)	17/135 (13%)	0.3718 (0.1415, 0.9770) /0.045	-7.5078 (-14.3658, -0.6499) /0.032	0.4038 (0.1646, 0.9905) /0.048	0.044
Europe	11/165 (7%)	16/155 (10%)	0.6205 (0.2785, 1.3827) /0.243	-3.6559 (-9.7738, 2.4620) /0.242	0.6458 (0.3095, 1.3478) /0.244	
Rest of World	3/ 44 (7%)	0/ 37	>999 (>999, >999) /NC	8.9078 (-24.6793, 42.4948) /0.603	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	5/118 (4%)	10/135 (7%)	0.5531 (0.1835, 1.6670) /0.293	-3.1701 (-8.8908, 2.5506) /0.277	0.5720 (0.2012, 1.6261) /0.295	0.625
Europe	2/165 (1%)	8/155 (5%)	0.2255 (0.0471, 1.0788) /0.062	-3.9492 (-7.8117, -0.0866) /0.045	0.2348 (0.0507, 1.0888) /0.064	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
North America	5/118 (4%)	9/135 (7%)	0.6195 (0.2017, 1.9030) /0.403	-2.4294 (-7.9895, 3.1308) /0.392	0.6356 (0.2191, 1.8437) /0.404	0.284
Europe	1/165 (<1%)	8/155 (5%)	0.1120 (0.0138, 0.9065) /0.040	-4.5552 (-8.2341, -0.8764) /0.015	0.1174 (0.0149, 0.9280) /0.042	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pyrexia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site swelling						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site warmth						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site discolouration						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	0/118	2/135 (1%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	2/ 44 (5%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Diverticulitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis E						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epididymitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Acute hepatitis B						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Anal abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Erysipelas						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abdominal pain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oroantral fistula						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Pain in extremity						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Muscle spasms						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Intervertebral disc protrusion						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteoarthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Osteonecrosis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Cerebrovascular accident						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Major depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Contusion						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Body temperature increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Transaminases increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
White blood cell count decreased						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tympanic membrane perforation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

PPD

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Retinal detachment						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypercholesterolaemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 3

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute hepatitis B						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epiglottitis obstructive						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.21

Analysis of Proportion of Subjects with Adverse Events by Maximum Toxicity Grade, System Organ Class and Preferred Term (Maintenance Phase) - by Region - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Maximum Toxicity Grade= 4

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group.

Note: OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates. NC = Not Calculable.

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Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	5/ 84 (6%)	8/ 98 (8%)	0.7120 (0.2238, 2.2656) /0.565	-2.2109 (-9.6262, 5.2045) /0.559	0.7292 (0.2479, 2.1443) /0.566	0.807
35 - <50	11/154 (7%)	15/143 (10%)	0.6564 (0.2909, 1.4811) /0.311	-3.3467 (-9.8094, 3.1161) /0.310	0.6810 (0.3236, 1.4329) /0.311	
>=50	6/ 89 (7%)	12/ 86 (14%)	0.4458 (0.1593, 1.2472) /0.124	-7.2119 (-16.1990, 1.7752) /0.116	0.4831 (0.1898, 1.2296) /0.127	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	0/ 84	4/ 98 (4%)	<0.0001 (<0.0001, -) />0.999	-6.2907 (-28.4646, 15.8832) /0.578	<0.0001 (<0.0001, -) />0.999	0.238
35 - <50	5/154 (3%)	8/143 (6%)	0.5663 (0.1809, 1.7730) /0.329	-2.3477 (-7.0406, 2.3453) /0.327	0.5804 (0.1944, 1.7329) /0.330	
>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Injection site pain						
<35	0/ 84	3/ 98 (3%)	<0.0001 (<0.0001, -) />0.999	-5.3085 (-27.4475, 16.8305) /0.638	<0.0001 (<0.0001, -) />0.999	0.405
35 - <50	4/154 (3%)	8/143 (6%)	0.4500 (0.1325, 1.5281) /0.200	-2.9970 (-7.5245, 1.5305) /0.194	0.4643 (0.1429, 1.5086) /0.202	
>=50	2/ 89 (2%)	6/ 86 (7%)	0.3065 (0.0601, 1.5626) /0.155	-4.7296 (-10.9321, 1.4730) /0.135	0.3221 (0.0668, 1.5523) /0.158	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				
Chest pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Fatigue						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site warmth						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Infections and infestations						
Any Event						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Anal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Epididymitis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epiglottitis obstructive						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Erysipelas						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis E						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				
Arthralgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Costochondritis						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Muscle spasms						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Osteoarthritis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Osteonecrosis						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Pain in extremity						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	0/ 86				
Abdominal pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal haemorrhage						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Oroantral fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
<35	2/ 84 (2%)	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Body temperature increased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
White blood cell count decreased						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	1/ 84 (1%)	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Contusion						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Depression						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Acute myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tympanic membrane perforation						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Retinal detachment						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterol aemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Cerebrovascular accident						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal and urinary disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Renal colic						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	3/ 73 (4%)	6/ 75 (8%)	0.4929 (0.1185, 2.0497) /0.331	-3.8904 (-11.5347, 3.7538) /0.319	0.5137 (0.1334, 1.9774) /0.333	0.749
Male	19/254 (7%)	29/252 (12%)	0.6217 (0.3389, 1.1406) /0.125	-4.0276 (-9.1257, 1.0705) /0.122	0.6500 (0.3744, 1.1285) /0.126	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.245
Male	7/254 (3%)	16/252 (6%)	0.4180 (0.1689, 1.0343) /0.059	-3.5933 (-7.2151, 0.0285) /0.052	0.4341 (0.1817, 1.0370) /0.060	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
Female	0/ 73	2/ 75 (3%)	<0.0001 (<0.0001, -) />0.999	-4.9265 (-28.7735, 18.9206) /0.686	<0.0001 (<0.0001, -) />0.999	0.264
Male	6/254 (2%)	15/252 (6%)	0.3823 (0.1459, 1.0017) /0.050	-3.5902 (-7.0574, -0.1229) /0.042	0.3969 (0.1565, 1.0064) /0.052	
Injection site discomfort						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Fatigue						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site discolouration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injection site warmth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Pyrexia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	4/254 (2%)	5/252 (2%)				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Diverticulitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Epididymitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Epiglottitis obstructive						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Erysipelas						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Hepatitis E						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Pneumonia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	3/254 (1%)	2/252 (<1%)				
Intervertebral disc protrusion						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Costochondritis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Muscle spasms						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Osteoarthritis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Osteonecrosis						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Rotator cuff syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Abdominal pain						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Haemorrhoidal haemorrhage						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Oroantral fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	2/254 (<1%)	0/252				
Body temperature increased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
White blood cell count decreased						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Contusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	1/252 (<1%)				
Depression						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Cardiac disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Ear and labyrinth disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Eye disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Retinal detachment						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Immune system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Metabolism and nutrition disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolemia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nervous system disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebrovascular accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Renal and urinary disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
Female	0 / 73	0 / 75				
Male	0 / 254	1 / 252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	15/238 (6%)	29/256 (11%)	0.5265 (0.2748, 1.0087) /0.053	-5.0256 (-9.9859, -0.0653) /0.047	0.5564 (0.3060, 1.0116) /0.055	0.401
Non-White	7/ 89 (8%)	6/ 71 (8%)	0.9248 (0.2964, 2.8858) /0.893	-0.5855 (-9.1375, 7.9665) /0.893	0.9307 (0.3274, 2.6460) /0.893	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	5/238 (2%)	17/256 (7%)	0.3017 (0.1095, 0.8311) /0.020	-4.5398 (-8.0926, -0.9869) /0.012	0.3164 (0.1186, 0.8441) /0.022	0.201
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
White	4/238 (2%)	16/256 (6%)	0.2564 (0.0845, 0.7783) /0.016	-4.5693 (-7.9545, -1.1841) /0.008	0.2689 (0.0912, 0.7929) /0.017	0.165
Non-White	2/ 89 (2%)	1/ 71 (1%)	1.6092 (0.1429, 18.1147) /0.700	0.8387 (-3.2837, 4.9612) /0.690	1.5955 (0.1476, 17.2412) /0.700	
Injection site discomfort						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chest pain						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Fatigue						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site discolouration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site warmth						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pyrexia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	3/238 (1%)	2/256 (<1%)				
Non-White	2/ 89 (2%)	3/ 71 (4%)				
Acute hepatitis B						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Anal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Diverticulitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Epididymitis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epiglottitis obstructive						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Erysipelas						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Hepatitis E						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Pneumonia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	3/238 (1%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Intervertebral disc protrusion						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Arthralgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Costochondritis						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Muscle spasms						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Myalgia						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Osteoarthritis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Osteonecrosis						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pain in extremity						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Rotator cuff syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Abdominal pain						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal haemorrhage						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Oroantral fistula						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Investigations						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				
Body temperature increased						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
White blood cell count decreased						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Contusion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Diffuse large B-cell lymphoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Glioblastoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	0/ 89	0/ 71				
Depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Major depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Blood and lymphatic system disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Microcytic anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Cardiac disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute myocardial infarction						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Ear and labyrinth disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Tympanic membrane perforation						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Eye disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Retinal detachment						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Immune system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Metabolism and nutrition disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolemia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Nervous system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebrovascular accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Renal and urinary disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Renal colic						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	7/118 (6%)	18/135 (13%)	0.4099 (0.1649, 1.0192) /0.055	-7.4011 (-14.5459, -0.2563) /0.042	0.4449 (0.1926, 1.0279) /0.058	0.051
Europe	12/165 (7%)	17/155 (11%)	0.6367 (0.2936, 1.3805) /0.253	-3.6950 (-10.0118, 2.6217) /0.252	0.6631 (0.3274, 1.3430) /0.254	
Rest of World	3/ 44 (7%)	0/ 37	>999 (>999, >999) /NC	8.9078 (-24.6793, 42.4948) /0.603	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	5/118 (4%)	10/135 (7%)	0.5531 (0.1835, 1.6670) /0.293	-3.1701 (-8.8908, 2.5506) /0.277	0.5720 (0.2012, 1.6261) /0.295	0.625
Europe	2/165 (1%)	8/155 (5%)	0.2255 (0.0471, 1.0788) /0.062	-3.9492 (-7.8117, -0.0866) /0.045	0.2348 (0.0507, 1.0888) /0.064	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
North America	5/118 (4%)	9/135 (7%)	0.6195 (0.2017, 1.9030) /0.403	-2.4294 (-7.9895, 3.1308) /0.392	0.6356 (0.2191, 1.8437) /0.404	0.284
Europe	1/165 (<1%)	8/155 (5%)	0.1120 (0.0138, 0.9065) /0.040	-4.5552 (-8.2341, -0.8764) /0.015	0.1174 (0.0149, 0.9280) /0.042	
Rest of World	0/ 44	0/ 37	NC	NC	NC	

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site discomfort						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Chest pain						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fatigue						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site discolouration						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site warmth						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Infections and infestations						
Any Event						
North America	1/118 (<1%)	3/135 (2%)				
Europe	2/165 (1%)	2/155 (1%)				
Rest of World	2/ 44 (5%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Anal abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Epididymitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Epiglottitis obstructive						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Erysipelas						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hepatitis E						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Pneumonia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Musculoskeletal and connective tissue disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
Europe	3/165 (2%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				
Arthralgia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Costochondritis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Muscle spasms						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Myalgia						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Osteoarthritis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Osteonecrosis						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Pain in extremity						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Rotator cuff syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Abdominal pain						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Haemorrhoidal haemorrhage						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Oroantral fistula						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Investigations						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Body temperature increased						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
White blood cell count decreased						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Contusion						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Overdose						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diffuse large B-cell lymphoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Major depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Microcytic anaemia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Acute myocardial infarction						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Ear and labyrinth disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Tympanic membrane perforation						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Eye disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Retinal detachment						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Metabolism and nutrition disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypercholesterolemia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Cerebrovascular accident						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Abortion spontaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Renal and urinary disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Renal colic						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.22

Analysis of Proportion of Subjects with Severe Adverse Events (Maximum Grade 3 or 4) by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	3/ 84 (4%)	0/ 98	>999 (>999, >999) /NC	5.8004 (-14.9617, 26.5626) /0.584	>999 (>999, >999) /NC	0.069
35 - <50	7/154 (5%)	8/143 (6%)	0.8036 (0.2838, 2.2756) /0.681	-1.0490 (-6.0500, 3.9521) /0.681	0.8125 (0.3024, 2.1834) /0.681	
>=50	7/ 89 (8%)	3/ 86 (3%)	2.3618 (0.5903, 9.4491) /0.224	4.3768 (-2.4288, 11.1824) /0.207	2.2547 (0.6025, 8.4371) /0.227	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	3/ 84 (4%)	0/ 98				
35 - <50	4/154 (3%)	5/143 (3%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pneumonia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Acute hepatitis B						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal abscess						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Diverticulitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Epiglottitis obstructive						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Erysipelas						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastroenteritis						
Escherichia coli						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Peritonsillar abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Sialoadenitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Sinusitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	2/154 (1%)	1/143 (<1%)				
>=50	2/ 89 (2%)	0/ 86				
Haemorrhoids						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal fistula						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Colitis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Oroantral fistula						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
<35	0 / 84	0 / 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1 / 89 (1%)	0 / 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Head injury						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Overdose						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Intervertebral disc protrusion						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Rotator cuff syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
 Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cerebral infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				
Cerebrovascular accident						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Microcytic anaemia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Acute myocardial infarction						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Abortion spontaneous						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
<35	0 / 84	0 / 98				
35 - <50	0 / 154	1 / 143 (<1%)				
>=50	0 / 89	0 / 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Priapism						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep apnoea syndrome						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	2/ 73 (3%)	3/ 75 (4%)	0.6761 (0.1097, 4.1683) /0.673	-1.2603 (-7.0646, 4.5441) /0.670	0.6849 (0.1178, 3.9809) /0.673	0.309
Male	15/254 (6%)	8/252 (3%)	1.9142 (0.7968, 4.5985) /0.146	2.7309 (-0.8871, 6.3489) /0.139	1.8602 (0.8029, 4.3098) /0.148	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Infestations and infestations						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)	1.0278 (0.0631, 16.7455) /0.985	0.0365 (-3.6848, 3.7578) /0.985	1.0274 (0.0655, 16.1197) /0.985	0.843
Male	7/254 (3%)	5/252 (2%)	1.4000 (0.4384, 4.4709) /0.570	0.7718 (-1.8773, 3.4209) /0.568	1.3890 (0.4467, 4.3185) /0.570	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pneumonia						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Anal abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diverticulitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Epiglottitis obstructive						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Erysipelas						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastroenteritis Escherichia coli						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injection site abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Peritonsillar abscess						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Sialoadenitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sinusitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
Female	0 / 73	0 / 75				
Male	4 / 254 (2%)	1 / 252 (<1%)				
Haemorrhoids						
Female	0 / 73	0 / 75				
Male	2 / 254 (<1%)	0 / 252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Colitis						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Oroantral fistula						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				
Head injury						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Overdose						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	2/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Intervertebral disc protrusion						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Rotator cuff syndrome						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Diffuse large B-cell lymphoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Nervous system disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cerebral infarction						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Cerebrovascular accident						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Microcytic anaemia						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cardiac disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Acute myocardial infarction						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Immune system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Abortion spontaneous						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Reproductive system and breast disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Priapism						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sleep apnoea syndrome						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	11/238 (5%)	9/256 (4%)	1.3299 (0.5411, 3.2684) /0.534	1.1062 (-2.3874, 4.5998) /0.535	1.3147 (0.5546, 3.1163) /0.534	0.500
Non-White	6/ 89 (7%)	2/ 71 (3%)	2.4940 (0.4877, 12.7525) /0.272	3.9247 (-2.5521, 10.4014) /0.235	2.3933 (0.4981, 11.4992) /0.276	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	4/238 (2%)	4/256 (2%)				
Non-White	4/ 89 (4%)	2/ 71 (3%)				
Pneumonia						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Acute hepatitis B						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Anal abscess						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Diverticulitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Epiglottitis obstructive						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Erysipelas						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Gastroenteritis Escherichia coli						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Peritonsillar abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Sialoadenitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Sinusitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gastrointestinal disorders						
Any Event						
White	2/238 (<1%)	1/256 (<1%)				
Non-White	2/ 89 (2%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Haemorrhoids						
White	0/238	0/256				
Non-White	2/ 89 (2%)	0/ 71				
Anal fistula						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Colitis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Oroantral fistula						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injury, poisoning and procedural complications						
Any Event						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Head injury						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Overdose						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
White	2/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Intervertebral disc protrusion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rotator cuff syndrome						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Diffuse large B-cell lymphoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glioblastoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Nervous system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cerebral infarction						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Cerebrovascular accident						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Microcytic anaemia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cardiac disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Acute myocardial infarction						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Immune system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Abortion spontaneous						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Reproductive system and breast disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Priapism						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Sleep apnoea syndrome						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	3/118 (3%)	3/135 (2%)	1.1478 (0.2272, 5.7984) /0.868	0.3202 (-3.4546, 4.0949) /0.868	1.1441 (0.2354, 5.5607) /0.867	0.037
Europe	8/165 (5%)	8/155 (5%)	0.9363 (0.3426, 2.5591) /0.898	-0.3128 (-5.0953, 4.4697) /0.898	0.9394 (0.3614, 2.4415) /0.898	
Rest of World	6/ 44 (14%)	0/ 37	>999 (>999, >999) /NC	15.4033 (-18.7108, 49.5175) /0.376	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
North America	3/118 (3%)	3/135 (2%)				
Europe	2/165 (1%)	3/155 (2%)				
Rest of World	3/ 44 (7%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pneumonia						
North America	0/118	1/135 (<1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Acute hepatitis B						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal abscess						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Diverticulitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Epiglottitis obstructive						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Erysipelas						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastroenteritis Escherichia coli						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Peritonsillar abscess						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Sialoadenitis						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Sinusitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	2/165 (1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				
Haemorrhoids						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Anal fistula						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Colitis						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Oroantral fistula						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injury, poisoning and procedural complications						
Any Event						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Head injury						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Overdose						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/118	0/135				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Intervertebral disc protrusion						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Rotator cuff syndrome						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
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 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Diffuse large B-cell lymphoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Nervous system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Cerebral infarction						
North America	0/118	0/135				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Cerebrovascular accident						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Blood and lymphatic system disorders						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Microcytic anaemia						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Cardiac disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Acute myocardial infarction						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Immune system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pregnancy, puerperium and perinatal conditions						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Abortion spontaneous						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Reproductive system and breast disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Priapism						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Respiratory, thoracic and mediastinal disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.23
 Analysis of Proportion of Subjects with Serious Adverse Events (Excluding Deaths)
 by System Organ Class and Preferred Term (Maintenance Phase)
 - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Sleep apnoea syndrome						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
<35	2/ 84 (2%)	2/ 98 (2%)				
35 - <50	3/154 (2%)	5/143 (3%)				
>=50	4/ 89 (4%)	4/ 86 (5%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	2/154 (1%)	2/143 (1%)				
>=50	3/ 89 (3%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site pain						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				
Fatigue						
<35	0/ 84	1/ 98 (1%)				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Pyrexia						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Asthenia						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site discolouration						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Injection site necrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site nodule						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Injection site swelling						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
<35	2/ 84 (2%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Acute hepatitis B						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Influenza						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
<35	1/ 84 (1%)	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	2/143 (1%)				
>=50	0/ 89	1/ 86 (1%)				
Headache						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Dizziness						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Presyncope						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	1/143 (<1%)				
>=50	1/ 89 (1%)	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hyperhidrosis						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	1/ 86 (1%)				
Rash maculo-papular						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Skin lesion						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	1/ 89 (1%)	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				
Abnormal dreams						
<35	0/ 84	0/ 98				
35 - <50	0/154	2/143 (1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Depression						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				
Insomnia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Sleep disorder						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Diffuse large B-cell lymphoma						
<35	0/ 84	0/ 98				
35 - <50	1/154 (<1%)	0/143				
>=50	0/ 89	0/ 86				
Glioblastoma						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Gastrointestinal disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				
Nausea						
<35	0/ 84	0/ 98				
35 - <50	0/154	0/143				
>=50	0/ 89	1/ 86 (1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				
Investigations						
Any Event						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
<35	0/ 84	1/ 98 (1%)				
35 - <50	0/154	0/143				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by
 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Age (years) (<35 vs. 35 - <50 vs. >=50)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myalgia						
<35	0/ 84	0/ 98				
35 - <50	0/154	1/143 (<1%)				
>=50	0/ 89	0/ 86				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
Female	3/ 73 (4%)	4/ 75 (5%)	0.7607 (0.1642, 3.5234) /0.727	-1.2237 (-8.0500, 5.6025) /0.725	0.7705 (0.1786, 3.3241) /0.727	0.915
Male	6/254 (2%)	7/252 (3%)	0.8468 (0.2806, 2.5556) /0.768	-0.4156 (-3.1733, 2.3421) /0.768	0.8504 (0.2898, 2.4952) /0.768	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	4/254 (2%)	4/252 (2%)				
Injection site pain						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	3/252 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Fatigue						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Pyrexia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Asthenia						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Chills						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Injection site discolouration						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injection site hypersensitivity						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				
Injection site nodule						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site swelling						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Injection site warmth						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
Female	1/ 73 (1%)	1/ 75 (1%)				
Male	1/254 (<1%)	1/252 (<1%)				
Acute hepatitis B						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Influenza						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Injection site abscess						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	1/254 (<1%)	2/252 (<1%)				
Headache						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Disturbance in attention						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Dizziness						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Presyncope						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
Female	1/ 73 (1%)	0/ 75				
Male	1/254 (<1%)	2/252 (<1%)				
Hyperhidrosis						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Rash maculo-papular						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				
Skin lesion						
Female	1/ 73 (1%)	0/ 75				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	3/252 (1%)				
Abnormal dreams						
Female	0/ 73	0/ 75				
Male	0/254	2/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Insomnia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Sleep disorder						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	1/252 (<1%)				
Diffuse large B-cell lymphoma						
Female	0/ 73	0/ 75				
Male	1/254 (<1%)	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glioblastoma						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Gastrointestinal disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Nausea						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				
Immune system disorders						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Investigations						
Any Event						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
Female	0/ 73	1/ 75 (1%)				
Male	0/254	0/252				
Musculoskeletal and connective tissue disorders						
Any Event						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Sex at Birth (Female vs. Male)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)
Myalgia						
Female	0/ 73	0/ 75				
Male	0/254	1/252 (<1%)				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
White	7/238 (3%)	8/256 (3%)	0.9394 (0.3353, 2.6315) /0.905	-0.1838 (-3.2088, 2.8411) /0.905	0.9412 (0.3466, 2.5556) /0.905	0.578
Non-White	2/ 89 (2%)	3/ 71 (4%)	0.5211 (0.0847, 3.2067) /0.482	-1.9782 (-7.5797, 3.6233) /0.489	0.5318 (0.0913, 3.0968) /0.482	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

General disorders and administration site conditions						
Any Event						
White	4/238 (2%)	2/256 (<1%)				
Non-White	1/ 89 (1%)	2/ 71 (3%)				
Injection site pain						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Fatigue						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Pyrexia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Asthenia						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Chills						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Injection site discolouration						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site hypersensitivity						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site necrosis						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site nodule						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site swelling						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				
Injection site warmth						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Infections and infestations						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Acute hepatitis B						
White	0/238	0/256				
Non-White	1/ 89 (1%)	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Influenza						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Injection site abscess						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
White	0/238	2/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Headache						
White	0/238	1/256 (<1%)				
Non-White	1/ 89 (1%)	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Disturbance in attention						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Dizziness						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Presyncope						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	1/ 89 (1%)	1/ 71 (1%)				
Hyperhidrosis						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Rash maculo-papular						
White	0/238	0/256				
Non-White	1/ 89 (1%)	0/ 71				
Skin lesion						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by
 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Psychiatric disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	2/ 71 (3%)				
Abnormal dreams						
White	0/238	0/256				
Non-White	0/ 89	2/ 71 (3%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
Depression						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Insomnia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				
Sleep disorder						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
White	1/238 (<1%)	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Diffuse large B-cell lymphoma						
White	1/238 (<1%)	0/256				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Glioblastoma						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Gastrointestinal disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nausea						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Immune system disorders						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24

Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Hypersensitivity						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Investigations						
Any Event						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
White	0/238	1/256 (<1%)				
Non-White	0/ 89	0/ 71				
Musculoskeletal and connective tissue disorders						
Any Event						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by
 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Race (White vs. Non-White)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Myalgia						
White	0/238	0/256				
Non-White	0/ 89	1/ 71 (1%)				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Overall						
Any Event						
North America	3/118 (3%)	6/135 (4%)	0.5609 (0.1371, 2.2939) /0.421	-1.9021 (-6.3910, 2.5869) /0.406	0.5720 (0.1463, 2.2371) /0.422	0.417
Europe	5/165 (3%)	5/155 (3%)	0.9375 (0.2661, 3.3032) /0.920	-0.1955 (-4.0136, 3.6226) /0.920	0.9394 (0.2773, 3.1821) /0.920	
Rest of World	1/ 44 (2%)	0/ 37	>999 (>999, >999) /NC	NC	>999 (>999, >999) /NC	

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

General disorders and administration site conditions						
Any Event						
North America	3/118 (3%)	4/135 (3%)				
Europe	2/165 (1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site pain						
North America	1/118 (<1%)	3/135 (2%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Fatigue						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Pyrexia						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Asthenia						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Chills						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site discolouration						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site hypersensitivity						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Injection site necrosis						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Injection site nodule						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Injection site swelling						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site warmth						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Infestations and infestations						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	1/ 44 (2%)	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Acute hepatitis B						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	1/ 44 (2%)	0/ 37				
Influenza						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Injection site abscess						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Nervous system disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				
Headache						
North America	1/118 (<1%)	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Disturbance in attention						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Dizziness						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)
-----	-----	-----	-----	-----	-----	-----
Presyncope						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Skin and subcutaneous tissue disorders						
Any Event						
North America	1/118 (<1%)	2/135 (1%)				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hyperhidrosis						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Rash maculo-papular						
North America	1/118 (<1%)	0/135				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by
 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Skin lesion						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Psychiatric disorders						
Any Event						
North America	0/118	3/135 (2%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Abnormal dreams						
North America	0/118	2/135 (1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Depression						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Insomnia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Sleep disorder						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)						
Any Event						
North America	0/118	0/135				
Europe	1/165 (<1%)	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

Table 3.24
 Analysis of Proportion of Subjects with Adverse Events Leading to Treatment Discontinuation by System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Diffuse large B-cell lymphoma						
North America	0/118	0/135				
Europe	1/165 (<1%)	0/155				
Rest of World	0/ 44	0/ 37				
Glioblastoma						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class Preferred Term	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Gastrointestinal disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				
Nausea						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Immune system disorders						
Any Event						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Hypersensitivity						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Investigations

Any Event

North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.

Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Transaminases increased						
North America	0/118	0/135				
Europe	0/165	1/155 (<1%)				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter-action p-value (RR)

Musculoskeletal and connective tissue disorders						
Any Event						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.

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 System Organ Class and Preferred Term (Maintenance Phase) - by Subgroup - ATLAS-2M
 (Prior CAB + RPV of 0 Weeks)

Subgroup: Region (North America vs. Europe vs. Rest of World)

System Organ Class	Q8W (N=327)	Q4W (N=327)	OR (95%CI) /p-value	RD (95%CI) /p-value	RR (95%CI) /p-value	Inter- action p-value (RR)

Myalgia						
North America	0/118	1/135 (<1%)				
Europe	0/165	0/155				
Rest of World	0/ 44	0/ 37				

Note: "Any Event" represents subjects with any AE reported.
 Note: By-subgroup OR, RD, RR and p-values are not provided when all levels of the subgroup have number of events less than 10 regardless of treatment group. OR = Odds Ratio; RD = Risk Difference (in percentages); RR = Relative Risk. For each SOC and PT, RD, OR and RR for each subgroup are obtained from genmod models (link = identity, logit or log, respectively), using a 'by subgroup statement'. P-value for interaction is for RR only and is obtained by genmod models with the following variables: treatment, subgroup, subgroup*treatment with no covariate adjustment. NC = Not Calculable. Zero counts for AEs in either treatment group may lead to unreliable statistical estimates.